Diagnostics for Low- and Middle-Income Countries (LMICs) Conference

Maison Française d'Oxford
27-28 March 2023

Conference Programme				
Date	**Time**	**Session**	**Title**	**Speaker**
Monday 27 March	09:00-09:10	Welcome to the Conference		Prof Lionel Tarassenko
	09:10-09:30	1	Why this conference is important	Dr Ken Fleming
	09:30-10:00	2: The opportunities and challenges of engineering and implementing point of care tests in LMICs	Going viral: Harnessing data science, diagnostics and nanomaterials for early detection of infectious diseases in LMICs.	Prof Rachel McKendry (Session Co-Chair)
	10:00-10:30		Acceptability and feasibility of implementing digitally connected tests in rural South Africa, insights from formative work.	Prof Maryam Shahmanesh
	10:30-11:00		Feasibility, acceptability and impact of HIV and COVID-19 self-testing: lessons learned from implementation research projects in Southern African countries	Dr Euphemia Sibanda
	11:00-11:30		Break	
	11:30-12:00		New frontiers in point-of-care diagnostics	Prof Molly Stevens
	12:00-12:30		Accelerating access to point of care tests in LMICs: Our experience exploring a new regulatory policy framework in Africa, Latin America and Asia.	Dr Noah Fongwen (Session Co-Chair)
	12:30-13:00		Panel - All Speakers	
	13:00-13:45	Lunch		
	13:45-14:15	3: Apps and health informatics	Co-designing and Co-owning Innovation - Pathways to Acceptance of New Diagnostic Technologies	Dr Gari Clifford
	14:15-14:45		Artificial Intelligence based Assessment oF health sYmptoms in TAnzania (AFYA Health Study): Its potential for Clinical Decision Support in Sub Saharan Africa	Dr Nahya Salim
	14:45-15:15		Product-driven innovation for the management of digital technology in global health	Dr Melek Somai

	15:15-15:45		Design and Implementation of Healthcare Diagnostics Systems for TB Control in Hard-to-Reach Communities	Dr Alastair Van Heerden
	15:45-16:15	Break		
	16:15-16:45	4: Industrial Perspectives	The SAMBA Journey	Dr Helen Lee
	16:45-17:15		Engineering Point-of-care Diagnostics in LMICs; Opportunities and challenges	Dr Laud Anthony Basing
	17:15-17:45		Overview of the Nanapore portfolio in diagnostics + deep dive into the work on TB	Prof Justin O'Grady & Dr Emma Stanton
	18:30-21:00	Conference Dinner at the Oxford Museum of Natural History		Dr Gordon Sanghera
Tuesday 28 March	09:00-09:30	5 & 6: Clinical Perspectives	Overview of the Session	Prof Chrystalina Antoniades
	09:30-10:00		Development of Highly Reliable Point of Care Diagnostics for Africa	Dr Jesse Gitaka
	10:00-10:30		Enhancing Patient Care through Pathology Lead Strategic Activation of Point-of-Care Testing	Dr Daniel Maina
	10:30-11:00		Malaria diagnostic resistance in routine case detection in a primary healthcare facility in Kenya	Dr Isabella Oyier
	11:00-11:30		Break	
	11:30-12:00		Using Self-Supervised Feature Learning to improve the use of Pulse Oximeter Signals to Predict Paediatric Hospitalization	Mr Paul Mwaniki
	12:00-12:30		Scaling Digital Transformation: The eyeSmart EMR experience at LVPEI	Dr Vipin Das
	12:30-13:00		Determining optimal ways to monitor and detect diabetes in low-resource settings: Locally-relevant evidence from Uganda	Dr Anxious Niwaha
	13:00-13:45		Lunch	
	13:45-14:15		AHOMKA: Advancing Hypertension Health Outcomes in LMICs with culturally-adapted Mobile Technology	Dr Jacques Kpodonu

	14:15-14:45		Scaling up of a primary care intervention for cardiovascular risk management in Indonesia	Dr Praveen Devarsetty
	14:45-15:15		Using low-cost digital technologies to deliver novel clinical solutions	Prof Andrew Farmer
	15:15-15:45	Break		
	15:45-16:15	7: Challenges of scaling up resources in LMIC settings	Sustainable POC Diagnostics Services for LMICs- Focus on Blind Spots	Prof Tivani Mashamba-Thompson
	16:15-1645		Social Entrepreneurship	Mr Philip Wilson
	16:45-17:15		Leveraging Electronic Medical Records for Diagnostics in LMICs	Dr Stephen Senkomago Musoke
	17:15-17:45		EHRs in LMICs	Dr Hamish Fraser
	17:45-18:00	8	What have we learnt?	Prof. Lionel Tarassenko

Conference Abstracts & Speaker Biographies

Session 1: Why this conference is important

Dr Ken Fleming

As the introduction to the conference, firstly I shall explain what diagnostics are and why they are vital for any effective efficient health care system. Secondly, I shall outline what the current situation for access to diagnostics is globally. Thirdly, I shall discuss why this is an opportune time to hold such a conference and lastly, I shall suggest why it is important to hold such a conference at all.

Diagnostics encompass a broad range of investigations/tests which are used not just to diagnose any particular condition, but, equally importantly, are vital for guidance of therapy, for prognostication and for monitoring the patient's continuing situation. They also have an important role in public health; e.g. cancer registries. Pathology (broadly defined) and Imaging are the two main modalities and both are central to effective, efficient universal health care (UHC).

Despite their important roles, global access to these modalities is poor, with data from the recently published *Lancet Commission on Diagnostics* showing that around 80% of the population in LMICs have little or no access to even the simplest diagnostics. The lack is most severe at the primary care/community level.

Addressing this situation is crucial and in recent years several events (especially the Covid-19 pandemic) have highlighted the importance of diagnostics and provided an unprecedented opportunity to redress the neglect of the past. While improving this situation will require a broad range of political, financial and capacity developments, amongst the most promising are the recent innovations in technology, especially digitalisation and point-of-care tests. These are opening up our ability to "democratise" diagnostics (e.g. self -testing and self-sampling), best exemplified by home testing for Covid 19 using lateral flow tests.

Maintaining and accelerating these technological advances depends crucially on seamless, frequent, informed and sustained interactions between the clinicians, with their varied clinical problems, and the scientists who are developing the novel methodologies capable of solving these problems. There are few, if any, fora for such interactions, especially those of an international and generalist nature. The Reuben Conference on Diagnostics for LMICs is an important new initiative to address this need.

Biography

Kenneth Fleming has been a clinical academic pathologist with over 200 publications on liver pathology and on molecular patho-biology (H-index 52). He has had several major leadership positions, including Dean of Medicine, University of Oxford, 2000 – 2008.

Since 2008, he has been addressing the lack of diagnostics globally, including being Director of International Affairs, RCPath, 2011-14 and Pathology Adviser to

the Centre for Global Health NCI, Washington DC, 2015-18. Most recently he has chaired the Lancet Commission on Diagnostics which published its report in October 2021. He is currently on the scientific advisory group of the WHO Essential Diagnostics List and the Exemplars for Global Health, Gates Foundation.

Session 2: The opportunities and challenges of engineering and implementing point of care tests in LMICs

1. Accelerating access to point of care tests in LMICs: Our experience exploring a new regulatory policy framework in Africa, Latin America, and Asia

Dr Noah Fongwen

Noah Fongwen[1,2], David Heymann[2], Rosanna Peeling[2]

[1] Diagnostics Access Unit. Division of Laboratory Systems and Networks, Africa Centres for Disease Control and Prevention, Addis Ababa, Ethiopia.

[2] London School of Hygiene and Tropical Medicine

Rapid technological advances in recent decades and implementation studies have shown that there is often a mismatch between diagnostic products being marketed and public health needs leading to long wait times for critical decisions on regulatory approval and policy development as clearly demonstrated during the COVID-19 pandemic. The Accelerating Diagnostic Access Project (ADAP), funded by the Wellcome Trust was thus conceived and implemented through the International Diagnostics Centre at the London School of Hygiene and Tropical Medicine (LSHTM) and Chatham House (London). The goal of ADAP was to develop a regulatory-policy framework for ensuring more timely licensing and introduction to use of quality-assured point of care (POC) diagnostic tests. The project was implemented from 1 February 2020 to 31 March 2022.

The project started with an industry consultation with Innovate UK to understand the views of the diagnostics industry on the obstacles that prevented rapid market entry of new diagnostic tests and how they could be overcome. After the industry consultation, regional consultations were organized in Africa in partnership with Africa CDC, Latin America in partnership with the Latin America Alliance for the development of in-vitro Diagnostics (ALADDiV), and in Asia with the Association of Southeast Asian Nations (ASEAN). These networks provided a health technology coalition (HTC) platform for continuous dialogue between regulators and policy makers on the need for an accelerated pathway for licensing, policy development and adoption of novel diagnostic tests. Dialogue was facilitated by ADAP-developed role play scenarios that illustrated the enormous human and economic costs of lengthy regulatory reviews and policy development.

Common themes that emerged from the industry consultation and regional ADAP-developed role play exercises to decrease the time from test development to use were:

- Need for mechanisms to prevent unnecessary duplication of clinical performance studies, such as diagnostic evaluation networks and data sharing across countries.

- Need to increase use of existing tools to accelerate access, such as Emergency Use Authorization, waiver lists, regulatory reliance,

convergence and harmonization, understanding that though these tools exist their uptake is slow.

- Correct the mismatch between diagnostic products being developed and marketed and public health needs that is a result of the lack of dialogue between product developers and public health experts early in the development pathway; and that is compounded by regulatory science and policy development not having kept pace with technological innovation.

- Need for governments to understand the true value of diagnostics instead of considering them as unnecessary costs to the healthcare system.

Some of the key outcomes of the project were:

- Establishment of regional networks to accelerate the evaluation of diagnostics and reducing the cost and duplication of clinical performance studies. For example, Africa CDC has set up a regional biobanking network and will be moving ahead with evaluations studies starting in 2023. Latin America is also establishing a functional regional network.

- Africa CDC is working with partners to develop a waiver list of diagnostics that are of critical importance to the continent.

- Development of a neutral platform to build capacity of regulators on regulatory reliance and best practices that can streamline regulatory approval. The platform will bring key stakeholders to discuss critical issues that will facilitate the adoption of point of care tests.

In summary, this Wellcome-Trust funded project has raised awareness on the relevance of a new regulatory policy framework in LMICs that can accelerate diagnostics access and improve public health. The project delivered key outcomes that will go a long way towards accelerating access to diagnostics in LMICs. As we transition into the second phase of the project, more funding will be needed to enable us build on the successes, strengthen partnerships and foster collaboration. We will also delve deeper into other critical areas such as the developing a 'Value of Diagnostics' report that will help policy makers have a clearer understanding of the true value of diagnostics.

Biography

Noah Fongwen is the head of diagnostics access at the Africa Centres for Disease Control and Prevention (Africa CDC) in Addis Ababa Ethiopia and a Clinical Research Fellow at the London School of Hygiene and Tropical Medicine (LSHTM). He is a global health expert skilled in advanced research methods, implementation science, economic evaluation of complex public health interventions, and point-of-care technologies. He has expertise in clinical medicine, laboratory medicine, public health, and health policy. He has been a project leader/coordinator in several projects, including the Wellcome Trust-

funded international project to explore a new regulatory policy framework to accelerate access to diagnostics. At the Africa CDC, he leads diagnostics development and evaluation, streamlining regulatory access, post-marketing surveillance, policy development, and community uptake. Before joining the London School and Africa CDC, he worked as a medical officer and public health specialist for the Ministry of Public Health in Cameroon. During this period, he led the implementation of quality assurance for HIV tests and community sensitization for chronic diseases and supported the expanded program for immunization.

As head of access at Africa CDC, he has contributed significantly to developing policy documents such as the Africa CDC biobanking manual and the manual for multi-disease surveillance in Africa. He has also been instrumental in setting up a network of biobanking and diagnostic evaluation sites across Africa. As the head of innovation at the Africa CDC innovation hub, he is leading a systemic review and continent-wide project to explore the role of telephone hotlines in outbreak response. This project will set up a network of telephone hotlines that can be leveraged to increase access to information and health services during outbreaks in Africa.

He has also been a WHO consultant in developing Target Product Profiles (TPPs) for diagnostics for NTDs such as Dengue, Yaws, and Mycetoma. He is also the WHO TDR Global coordinator for decentralizing TDR Global activities. He has more than 40 peer-reviewed publications, including book chapters and editorials.

2. Feasibility, acceptability and impact of HIV and COVID-19 self-testing: lessons learned from implementation research projects in Southern African countries

Dr Euphemia Sibanda

Euphemia Sibanda,[1,2] Augustine Choko,[2,3] Musonda Simwinga[4], Elizabeth Corbett[5], Frances M Cowan[1,2]

[1]CeSHHAR Zimbabwe, Harare, Zimbabwe; [2]Liverpool School of Tropical Medicine, Liverpool, United Kingdom; [3]Malawi Liverpool Wellcome Trust Clinical Research Programme, Blantyre, Malawi, [4]Zambart, Lusaka, Zambia, [5]London School of Hygiene & Tropical Medicine, London, United Kingdom

Background

Self-testing can increase timely access to disease diagnosis, enable novel delivery strategies, and is a key component of the World Health Organization (WHO) self-care strategy aimed at reaching universal health coverage goals. Prior to our Unitaid-funded STAR project (2015-20), no self-test kit had been recommended by WHO for use in LMICs. Systems for pre-qualifying self-test kits were not in place.

The high-level goals of the STAR project, http://hivstar.lshtm.ac.uk/ (Malawi, Zambia, Zimbabwe, South Africa, Eswatini and Lesotho) were to catalyse market entry for HIV self-testing (HIVST) by providing multi-country evidence to enable WHO guidelines, establish HIVST as policy in all project countries, tackle regulatory issues, and reduce the cost of HIVST kits below $2.50. We applied lessons learned to self-testing for COVID-19 in Africa.

Methods

In Zimbabwe, Zambia and Malawi, we conducted research to inform the introduction and scale up of HIVST, starting with formative work to explore acceptability, ability to self-test correctly/accurately, and preferences for models of distribution. This was followed by evaluations of models of providing HIVST, including impact, cost and cost-effectiveness, social benefits and harms.

In all three countries, ability to understand HIVST instructions for use was explored using cognitive interviews, while accuracy was explored using surveys where participants were observed while conducting self-tests, with comparison with professional tests. Findings from this formative work informed optimisation of instructions for use. We then determined the impact of different models of HIVST distribution, including cluster randomised trials of community-based distribution models that were run separately in each country. In Zimbabwe, we developed an mHealth tool to support distribution of self-tests and follow-up of people who have tested.

For COVID-19 self-testing, we conducted cognitive interviews and accuracy studies to inform optimisation of instructions for use as described above. Additionally, we conducted in-depth interviews among people who had self-tested to explore views on self-testing for COVID-19.

Major findings and lessons learned

For both HIV and COVID-19 self-tests, cognitive interviews demonstrated the importance of context-relevant optimisation of instructions for use, including use of locally understandable language and symbols and clear labelling to support

understanding of layout of instructions. In HIVST accuracy studies, agreement between oral fluid self-tests and professional tests in Zimbabwe, Malawi and Zambia was 92.3%, 99.3% and 99.1%, with sensitivity of between 93% and 100%, and specificity of between 92% and 99.6%. People in rural areas and those with lower literacy levels were less able to self-test correctly. Demonstrations (in-person or video) improved accuracy. In both Zimbabwe and Malawi, self-testing with blood-based self-tests was more difficult compared to oral fluid tests; final optimised instructions required in-person demonstration. Major challenges were related to sample collection.

Community-based distribution of self-tests achieved population level HIVST coverage of 50.2% in Zimbabwe, between 42.5% and 74.5% in Malawi, and 26% in Zambia. Community-based distribution of self-tests was associated with increases in initiation of HIV treatment in nearby public sector clinics of between 27% and 39% in three community-based trials in Zimbabwe and Malawi. All community-based distribution models were highly acceptable among communities. Coerced testing was reported by 1% to 5% of participants. There was low prevalence of reported serious social harms (only 1 report in over 80,000 HIVST kit distributions in Zimbabwe and 2 reports in over 80,000 distributions in Malawi). We found that despite specific messaging to discourage this, 11.6% of people living with HIV who were already on treatment retested for HIV during community-based distribution, which carries the risk of false negative results.

An mHealth tool was successfully developed to support HIVST distribution and contact of recipients of HIVST among students enrolled in tertiary education. However, although successful in supporting HIVST distribution, student interest in engaging with the tool post-test was low – only 8% completed an online questionnaire following testing.

By the end of STAR project 88 countries had HIVST policies, 4 HIVST kits were prequalified by WHO with the prices of kits ranging between US$1.50-$3.09.

For COVID-19 tests, in Zimbabwe and Malawi, final optimised instructions for COVID-19 also included in-person demonstration. In Zimbabwe and Malawi, we found almost 100% agreement between self-tests and professional tests for all test kits that were evaluated. Qualitative studies showed that self-testing for COVID-19 was highly acceptable in both countries. Our consortium is now conducting evaluations of different models of delivering self-tests for COVID-19 in Zimbabwe, Malawi and Nigeria.

Conclusions and next steps

Self-testing is feasible and acceptable in LMIC settings. Optimisation of instructions for use is important for supporting correct self-testing. Different models of delivering self-tests can be employed, with community-based models achieving great uptake and impact. Self-testing is a key component of self-care strategies that need to be employed to achieve universal health coverage. In ongoing projects in Zimbabwe, HIV self-testing is being used for supporting pharmacy-based distribution of pre-exposure prophylaxis for HIV and is part of a package of a self-care intervention for sexual and reproductive health among students enrolled in tertiary education. Lessons learned from HIV self-testing have catalysed introduction and adoption to policy of self-tests for other conditions/diseases such as COVID-19 and Hepatitis C.

Euphemia is an implementation science researcher who is based at Centre for Sexual Health and HIV AIDS Research (CeSHHAR(link is external)(opens in a new tab)) Zimbabwe, where she leads a portfolio of operational research studies on HIV and sexual & reproductive health. She joined LSTM as an honorary research fellow in December 2016 and was appointed Senior Lecturer in Global Health and Epidemiology in March 2019

Biography

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Euphemia has worked in HIV research since 2004. Much of her work has been implementation science research aimed at evaluating interventions at various points of the HIV continuum of care, including prevention of mother-to-child transmission of HIV, HIV testing and adoption of treatment and prevention strategies. In her evaluations, Euphemia has employed various research designs including individually randomised trials, cluster- randomised trials, and quasi-experimental studies, which almost always have built-in process evaluations involving qualitative research, which Euphemia is also comfortable with. Costing and cost-effectiveness analysis have also been important components of the studies Euphemia leads. Her research has included general populations in rural and urban communities and female sex workers.

Euphemia is a 2018 recipient of the MRC/DFID African Research Leader Fellowship.

3. Acceptability and feasibility of implementing digitally connected tests in rural South Africa, insights from formative work

Prof. Maryam Shahmanesh

Maryam Shahmanesh PhD FRCP: Director of Clinical Science, Africa Health Research Institute (South Africa), Professor of Global Health, UCL and NIHR Global Health Professor

Background

Despite effective biomedical interventions such as HIV Pre-Exposure Prophylaxis (PrEP) and universal HIV test and antiretroviral treatment (UTT) which eliminate HIV acquisition and transmission, HIV incidence in South Africa remains unacceptably high. Sub-optimal uptake of HIV testing and linkage to post-test services, particularly among young men and women outside antenatal settings, contributes to HIV incidence and HIV-related mortality in South Africa.

Methods

Between 2016 and 2022 we conducted a series of studies to use innovations in diagnostics, digital health, and peer support to decentralise and de-medicalise HIV testing and linkage to antiretroviral based HIV prevention and treatment (PrEP and UTT) amongst young people in rural KwaZulu-Natal, South Africa. In this talk we will present a few of these studies to illustrate our key findings and lessons learnt:

1) mAfrica: we conducted formative work to co-develop and pilot *Zenzele,* a mobile phone enabled HIV self-test to support decentralized HIV care and prevention. We conducted surveys with a representative sample of 13-35-year-olds (n=3460); provider and user interviews (n=40 and 54 respectively); and group discussion(n=9). We piloted *Zenzele,* a simulated online pathway with n=30 individuals aged 18-30 attending a rural clinic. The *Zenzele* application supported an audio-visual guide in isiZulu and English; a timer to support self-testing according to the manufacturer guidelines; photographing the test using the smartphone camera and providing an automated interpretation of the result (simulating the lateral flow test machine learning reader that we had developed); and post-test health promotion and linkage to care.

2)Stepping-stones and creating futures: This formative work aimed to develop participatory, dialogical HIV and gender-based violence interventions via digital platforms. We undertook 10 in-depth interviews with male Peer Navigators who had been extensively trained and working on a larger intervention promoting young people's sexual and reproductive rights. Interviews focused on their, and their peers', use of technology in their everyday lives. Data were transcribed and translated and subjected to thematic analysis.

3)Isisekelo Sempilo 2x2 factorial trial comparing self-collected specimens for sexually transmitted infection testing and referral to adolescent and youth friendly services (AYFS) for differentiated HIV with sexual and reproductive health, and/or referral to a peer navigator for tailored support, condom provision

and facilitation of AYFS attendance for differentiated HIV prevention compared to enhanced Standard of Care (SoC): referral to mobile adolescent youth friendly services (AYFS) on uptake of differentiated HIV prevention (UTT or PrEP) within 60 days of enrolment.

Key finding: During mAfrica we found 75.6% of 13-35-year-olds owned a mobile phone. After adjustment phone ownership was associated with age (aOR:1.48;95%CI1.42-1.54); male (aOR:1.64;95%CI 1.33-2.03); and recent HIV test (aOR:1.33;1.09-1.62). Interviews suggested that the mobile-phone enabled HIV-self testing was broadly acceptable to users and providers. During the pilot study, everyone completed the self-test and received a result, the majority without resorting to the online support. The one participant testing positive was successfully linked to care. Post-pilot interviews found that young people liked the privacy and convenience and valued the availability of a hotline nurse. Main challenges were variable digital literacy.

Stepping-stones and creating futures found structural barriers to the use of technology, including poor connectivity, high data costs, and erratic electricity. Young people primarily used Facebook and WhatsApp for communication, described a range of groups they were part of, and highlighted how reading messages asynchronously was important to overcome connectivity challenges. Peers shared how groups were primarily for information sharing, but also discussed 'sensitive' issues online. Privacy was a concern, especially for conversations and anonymity was seen as potentially supporting greater openness in these discussions. This study showed the potential to move beyond didactic mHealth information sharing approaches towards dialogical communication to be developed within the existing technological framework to strengthen HIV and gender-based violence prevention interventions.

Isisekelo Sempilo: 1743 (76%) eligible individuals were enrolled and randomised; n=732 (42.6%) linked to AFYS by 60 days. Those randomised to community-based STI self-sampling and testing were significantly more likely to uptake differentiated HIV care and prevention (aOR 1.61;95%CI:1.32-1.95) but peer-support had no effect.

Lessons learnt: Mobile phone enabled HIV self-testing combined the advantages of self-testing with provision of live support for those who struggle with the test, or who test positive. It provided the prospect of safe, decentralized, de-medicalised HIV care and prevention, including PrEP. Asynchronous mobile phone communication can enhance the action-reflection cycle and that greater anonymity could encourage further discussion and reflection, supporting the wider aims of dialogical interventions for gender-based violence and linkage to HIV care. Community-based STI self-sampling was acceptable and popular. Similar to HIV self-testing it improved access to diagnostics and in the case of STI self-sampling uptake of ART based HIV care and prevention. We hypothesize that digitally-enabled diagnostics, with or without peer support, may improve access to HIV testing and linkage to post-test HIV and SRH services and contributes to

reducing HIV incidence and HIV-related mortality, as well as improve sexual health amongst youth in rural South Africa.

Biography

Maryam Shahmanesh is a Professor of Global Health at the Institute for Global Health, University College London, Faculty on the executive committee of the the Africa Health Research Institute (South Africa) and an Honorary Consultant in Sexual Health and HIV Medicine at the Mortimer Market Centre. After graduating in Medicine (Cambridge University), she completed her specialist training in Sexual health and

HIV medicine (London). Her academic training, which has complemented her clinical training, includes a degree in Social and Political Science (Cambridge University), a Masters in Epidemiology (London School of Hygiene and Tropical Medicine), and a PhD in Clinical Epidemiology (University College London).

During her clinical and academic training, she spent two years as a project coordinator with Médecins sans Frontières in north Burma (1997-1999), where she gained extensive experience in evaluating, developing and implementing malaria, TB, HIV and sexual health services. Maryam's research interests are in the area of Global Health (UK, Burma, India, and South Africa) and have been supported by Wellcome Trust Clinical Training Fellowships, Walport (NIHR) Clinical lectureship, and a US NIH Early investigator award. Her key interest is to work with the multiple disciplines of social science, clinical medicine and epidemiology to develop and use innovative methods to rapidly evaluate complex interventions. Her experiences in Burma, India and South Africa, have provided her with ample experience in engaging and communicating with policy makers, stakeholders and communities, often in challenging and adverse conditions.

In addition to her research, Maryam is actively involved in postgraduate teaching. She has been the graduate teacher for taught programs; and has designed and led three Masters programmes at UCL, the Masters in Sexually Transmitted Infection and HIV (2010); the Masters in Population Health (2016); and the Masters in Applied Infectious Disease Epidemiology (2019). Maryam currently supervises PhD students (4) and is a mentor to a large team of South African early-career researchers. Maryam is also a clinician at one of the largest sexual health and HIV clinics in the UK.

4. New frontiers in point-of-care diagnostics

Prof. Molly Stevens

The Stevens group at Imperial College London's long-term goal is to ensure the future of diagnostics includes solutions which can be effective and affordable in LMICs. We use a materials science approach to engineer novel nanoparticle systems with unique properties that enable improved sensitivity over current alternatives. The REASSURED criteria are followed throughout the development of our point-of-care (PoC) diagnostic technologies,[1] ensuring our solutions are cost-effective, user-friendly and have the capability to capture data through mobile technologies that can be integrated into healthcare systems.[2] Work in the group has focused on the detection of HIV,[3] Malaria and Ebola among others.[4] Nanozymes, nanoparticles which exhibit catalytic activity similar to enzymes, are a key focus of the group, with platinum core-shell nanocatalysts (PtNCs) being a robust example.

PtNCs were first shown to be effective in the detection of p24, an early and highly conserved biomarker for HIV.[3] The assay was designed as a paper-based lateral flow immunoassay (LFIA) and resulted in an absorbance-based naked-eye detection of p24 spiked sera in the low femtomolar range (ca. 0.8 pg/mL) in under 20 minutes.[3] The catalytic amplification of the signal resulted in a 100-fold signal enhancement and a lower limit of detection compared to commercial alternatives, within the low-cost LFIA format. This biosensing platform is easily adaptable for the detection of other biomarkers for both infectious and noncommunicable diseases, work that is ongoing within the group.

Our malaria PoC test is a PtNC LFIA designed to detect activate gametocytes present in finger-prick blood samples and detect a gametocyte specific protein that is released during the egress process of gametocyte activation. By detecting mature and activatable gametocytes, we will be able to detect malaria in healthy individuals capable of transmitting the parasite, thereby delivering a tool for malaria eradication strategies.

A key issue for the development of our technologies is the availability of high affinity antibodies for novel biomarkers. This has led us to explore antibody alternatives, like affibodies, which can be more quickly produced against a new target and have other potential benefits for LMICs including better stability and longer shelf life. Future work in the group will focus on low-cost cholera detection in both water and stool samples. We are also working to commercialize this technology into a spin out company, Zyme Dx, with a strong impact and LMIC focus, acknowledging that the technology needs a viable route to translation to reach those who need it most.

1. Land KJ, Boeras DI, Chen XS, Ramsay AR, Peeling RW. REASSURED diagnostics to inform disease control strategies, strengthen health systems and improve patient outcomes. Vol. 4, Nature Microbiology. 2019.

2. Christopher S. Wood, Michael R. Thomas, Jobie Budd, Tivani P. Mashamba-Thompson, Kobus Herbst, Deenan Pillay, Rosanna W. Peeling, Anne M. Johnson, Rachel A. McKendry & Molly M.

Stevens, Taking connected mobile-health diagnostics of infectious diseases to the field. Vol 566, Nature. 2019.

3. Loynachan CN, Thomas MR, Gray ER, Richards DA, Kim J, Miller BS, et al. Platinum Nanocatalyst Amplification: Redefining the Gold Standard for Lateral Flow Immunoassays with Ultrabroad Dynamic Range. ACS Nano. 2018;12(1).

4. Polina Brangel, Ariel Sobarzo, Claudio Parolo, Benjamin S. Miller, Philip D. Howes, Sigal Gelkop, Julius J. Lutwama, John M. Dye, Rachel A. McKendry, Leslie Lobel, and Molly M. Stevens. A Serological Point-of-Care Test for the Detection of IgG Antibodies against Ebola Virus in Human Survivors. ACS Nano. 2018; 12 (1).

Biography

Molly M Stevens FREng FRS is Professor of Biomedical Materials and Regenerative Medicine and the Research Director for Biomedical Material Sciences in the Department of Materials, in the Department of Bioengineering and the Institute of Biomedical Engineering at Imperial College London. She graduated with a First-Class Honours BPharm degree from Bath University in 1995 and a PhD from the University of Nottingham in 2001. After postdoctoral research in the Langer Lab at MIT, she joined Imperial College London in 2004 as a lecturer and was promoted to Professor in 2008 as one of the youngest Professors ever in the history of the institution.

Molly's multidisciplinary research balances the investigation of fundamental science with the development of technology to address some of the major healthcare challenges. Her work has been instrumental in elucidating the bio-material interfaces. She has created a broad portfolio of designer biomaterials for applications in disease diagnostics and regenerative medicine. Her substantial body of work influences research groups around the world (>400 publications, h- index 98, >39k citations, 2018 and 2021 Clarivate Analytics Highly Cited Researcher in Cross- Field research).

Molly holds numerous leadership positions including Director of the UK Regenerative Medicine Platform "Smart Acellular Materials" Hub, Deputy Director of the EPSRC IRC in Early-Warning Sensing Systems for Infectious Diseases and Scientist Trustee of the National Gallery. She is Fellow of the Royal Society and the Royal Academy of Engineering (UK), Foreign Member of the National Academy of Engineering (USA) and International Honorary Member of the American Academy of Arts and Science.

5. Going viral: Harnessing data science, diagnostics and nanomaterials for early detection of infectious diseases in LMICs

Prof. Rachel McKendry

Director of i-sense EPSRC IRC in Agile Early Warning Sensing Systems for Infectious Diseases and Antimicrobial Resistance (www.i-sense.org.uk), London Centre for Nanotechnology and Division of Medicine, University College London

The COVID-19 pandemic has highlighted the enormous challenge of an emerging infectious disease, and the critical need for early disease detection and diagnosis, to protect patients and populations[1,2]. Diagnostics have emerged as a crucial counter-measure to the spread of COVID-19. By late 2022, more than 3 billion tests for SARS-CoV-2 had been conducted worldwide and yet only 0.4% occurred in low-income countries, raising ethical concerns about access and affecting our collective global ability to respond to the pandemic[2]. Moreover, COVID-19 typically presents high viral load (and antigen levels), which can be detected by currently available lateral flow tests; however, other diseases may prove more challenging to detect using these tests[2]. Neither lateral flow tests nor point-of-care tests currently exist for 50% of the World Health Organization's priority diseases of epidemic potential[2].

I will review recent advances in bioengineering which could help to widen access to high performance tests in LMIC settings, as well as the barriers to translation, adoption and implementation. Research from the i-sense EPSRC IRC programme in Agile Early Warning Sensing Systems for Infectious Diseases and Antimicrobial Resistance (www.i-sense.org.uk) will be presented. Research highlights include mHealth and deep learning algorithms to capture and classify HIV tests in partnership with the Africa Health Research Institute in KwaZulu-Natal, South Africa; our partnership with Africa CDC to inform the roll-out of mHealth approaches; deep learning algorithms of online search queries adopted by the UK Health Security Agency for COVID-19 and influenza surveillance; quantum nanodiamonds for ultra-sensitive HIV detection; and online care pathways to link patients to care[1-5]. I will conclude with a perspective on the wider research opportunities and challenges for decentralised testing and the future of public health in a digital age.

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Websites

i-sense EPSRC IRC in Agile Early Warning Sensing Systems for Infectious Diseases and AMR www.i-sense.org.uk

McKendry group website: https://themckendrylab.com/

UCL website: https://www.london-nano.com/our-people/our-people-bios/rachel-mckendry

Biography

Rachel McKendry is Professor of Biomedical Nanoscience and holds a joint position between the London Centre for Nanotechnology and Division of Medicine, University College London. She is Director of the £11M i-sense EPSRC IRC, a large interdisciplinary research collaboration in Early Warning Sensing Systems for Infectious Diseases. Her research lies at the cutting edge of nanotechnology, telecommunication, big data, infectious diseases and public health. Recent breakthroughs span from ultra-sensitive quantum nanodiamond diagnostics for virus detection (Miller et al Nature 587, 588 (2020)), nanomechanical sensors for antimicrobial resistance (Bennett et al ACS Sensors 5, 3132 (2020)), to deep learning models for rapid testing in partnership with the Africa Health Research Institute in South Africa. Her team led a major strategic review of the global use of digital technologies for COVID-19 (Budd et al Nature Medicine 26, 1183 (2020)).

Professor McKendry has won several awards for her research including the Royal Society Rosalind Franklin Award, Royal Society Wolfson Research Merit Award and the Institute of Physics Paterson Medal. She also co-chaired the Digital Medicine Theme of the Topol Review of the NHS, 'Preparing the Healthcare Workforce to Deliver the Digital Future' and led the Rosalind Franklin Appathon.

Session 3: Apps and health informatics

1. Co-designing and Co-owning Innovation - Pathways to Acceptance of New Diagnostic Technologies

Prof Gari Clifford

The design of scalable healthcare technologies in the Global North is predicated on high-resource environments, responsive supply chains and tolerance of failure. However, once a technology or company gains a foothold, there is little incentive to innovate. This model does not map well to low-resource settings, such as much of the Global South.

Although the World Health Organization recommends the ASSURED (affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free and deliverable to end-user) criteria to ensure robustness and scalability of devices, this approach has several limitations. In particular, both models of innovation do not consider the heterogeneous and non-fluid nature of supply chains in low-resource regions, where key components or infrastructure can change or become unavailable in unpredictable ways. Nor do they account for local innovation, improvisation and fabrication.

I argue that the chances of a successful innovation are increased by a co-design process that accounts for the local users' perspectives, and provides co-ownership, both intellectually and emotionally. Further, an open-source model for the technology enables scalability through adaptability in a complex and dynamic landscape. Finally, I discuss the potential for AI in point of care devices to address privacy, lack of connectivity, and healthcare workforce training.

Biography

Gari Clifford is a tenured Professor of Biomedical Informatics and Biomedical Engineering at Emory University and the Georgia Institute of Technology, and the Chair of the Department of Biomedical Informatics (BMI) at Emory. His research focuses on the application of signal processing and machine learning to medicine to classify, track and predict health and illness. His focus research areas include critical care, digital psychiatry, global health, mHealth, neuroinformatics and perinatal health.

After training in Theoretical Physics, he transitioned to AI and Engineering for his doctorate (DPhil) at the University of Oxford in the 1990's. He subsequently joined MIT as a postdoctoral fellow, then Principal Research Scientist where he managed the creation of the MIMIC II database, the largest open access critical care database in the world. He later returned as an Associate Professor of Biomedical Engineering to Oxford, where he helped found its Sleep & Circadian Neuroscience Institute and served as Director of the Centre for Doctoral Training in Healthcare Innovation at the Oxford Institute of Biomedical Engineering.

As Chair, Dr Clifford has established BMI as a leading center for critical care and mHealth informatics, and as a champion for open access data and open-source

software in medicine, particularly through his leadership of the PhysioNet/CinC Challenges and contributions to the PhysioNet Resource. Despite this, he is a strong supporter of commercial translation, working closely with industry, and serves as CTO of MindChild Medical, a spin-out from his research at MIT.

2. Artificial Intelligence based Assessment oF health sYmptoms in TAnzania (AFYA Health Study): Its potential for Clinical Decision Support in sub-Saharan Africa

Dr Nahya Salim

Nahya Salim[1], Marcel Schmude[2], Elizabeth Millen[2], Hila Azadzoy[2], Mustafa Bane[1], Lisa O'Donnell[2], Ewelina Türk[2], Ria Vaidya[2], Stephen Gilbert[2,3]

[1] Muhimbili University of Health and Allied Sciences (MUHAS), 9 United Nations Road, Upanga, P. O. Box 65001, Dar es Salaam, Tanzania

[2] Ada Health GmbH, Karl-Liebknecht-Str. 1, 10178 Berlin, Germany

[3] EKFZ for Digital Health, University Hospital Carl Gustav Carus Dresden, Technische Universität Dresden, Dresden, Germany

Background

Low- and middle-income countries (LMICs) face difficulties in providing adequate healthcare, one reason being the shortage of qualified health workers and an overwhelmed health system in primary health care. Artificial intelligence (AI)-based health apps are being developed to mitigate the pressure on the healthcare system.

The talk will describe a study that was conducted at Mbagala Rangi tatu district hospital, one of the busiest district hospitals at Temeke District, Dar-es-Salaam, Tanzania, focused on exploring the potential of an English language AI-based prototype diagnostic decision support system (DDSS) using a 'chatbot' for mid-level health care practitioners (HCP).

57 patients were enrolled in the study, which was conducted over a three-month period. In addition to their usual care visit, study participants had a consultation with a clinical officer using the AI chatbot, separated into two arms. In Arm 1, a preliminary differential diagnosis list (DDL) was created before seeing the DDSS's condition suggestion list. After being able to review both diagnosis lists, the mid-level HCP picked their top 5 differential diagnoses from both lists and submitted a final DDL. In Arm 2, the mid-level HCP saw the DDSS's condition suggestion list before submitting a final DDL. This gave the mid-level HCP the opportunity to take over differential diagnoses from the pDDSS and add their own differential diagnoses. The patient then proceeded to a consultation with a study-provided physician who completed a tablet-based structured electronic case report form.

The results showed that the mid-level Health Care Practitioners (HCPs) using the AI-based system had a higher accuracy and comprehensiveness in their diagnosis than the usual care HCPs close to study physicians. The study also showed that the AI-based system made the symptom assessment more efficient and the performance of the mid-level HCPs closer to highly-trained physicians. It was concluded that AI-based systems have potential in supporting mid-level HCPs in healthcare systems with a shortage of physicians.

Biography

Dr. Nahya Salim Masoud is a paediatrician, senior lecturer and Director of Research, Innovation and Publication at Muhimbili University of Health and Allied Sciences (MUHAS). She has a wide experience in the conduct of clinical trials specifically Malaria vaccine and drug trials. Dr. Nahya has a PhD in Epidemiology from University of Basel, Switzerland based on interaction and impact of Plasmodium and soil transmitted helminth co-infection among children living in endemic areas of Bagamoyo, coastal region of Tanzania. She has led several projects since 2007 in collaboration with Ifakara Health Institute (IHI) and Muhimbili University of Health and Allied Sciences. Her areas of expertise include vaccinology, health system research, epidemiology specifically on Malaria, helminths, respiratory and other infectious diseases. Currently, she is leading Newborn Essential Solutions and Technologies program (NEST 360) in Tanzania.

3. Product-driven innovation for the management of digital technology in global health

Dr Melek Somai

Most healthcare systems - across the globe, whether in high income countries or LMICs - struggle to navigate the innovation landscape, and their members are rarely aware that they need to apply the principles of business to the technology they employ. This stands in sharp contrast to what innovators, entrepreneurs, and digital health advocates believe is needed for healthcare systems to achieve their mission to improve the quality of care to patients while lowering cost.

Several digital health innovators, whom we work with, have shared how painful and excruciating it is to deliver valuable and scalable digital health solutions. The conclusion most commonly held is that the lack of a technological maturity is inherent to healthcare itself, being an industry of its own kind. In this talk I will explore novel practical theories of innovation and management that could contribute to help improve our design of solutions that leverage mHealth, digital health technologies, and point-of-care diagnostics.

Biography

Dr Melek Somai is an Assistant Professor of Medicine at the Medical College of Wisconsin. He holds also the role of the Chief Technology Officer of Inception Health - the innovation entity of Froedtert and the Medical College of Wisconsin health system. Dr Somai's expertise is in clinical informatics and data engineering. Dr Somai is trained in medicine, data scientist, and public health. He was formerly a research fellow at the Neuro-Epidemiology and Ageing Research and the Associate Director of the Centre for Cryptocurrency Research and Engineering exploring the deployment of Blockchain Technology in HealthCare and Life Sciences at Imperial College London. He is a former Fulbright scholar. Dr Somai has a special interest in the impact of information technology and data in shaping the provision of care globally. He is also interested in the development of new approaches to public and global health using data science. As part of his global health activities, Dr Somai is the founder and the current president of the Tunisian Center for Public Health.

4. Design and Implementation of Healthcare Diagnostics Systems for TB Control in Hard-to-Reach Communities

Prof. Alistair Van Heerden

The high prevalence of undetected tuberculosis (TB) in African communities poses a significant public health threat, causing prolonged infectiousness, delayed treatment, severe health consequences, and financial hardship. According to the WHO, 40% of incident cases in 2020 are underreported or underdiagnosed, especially in hard-to-reach communities with high TB/HIV burden. To address this issue, active case finding is crucial for high-risk groups such as people living with HIV or diabetes, miners, prisoners, and those living in high-burden, low-access areas. Two tests have potential as screening and triage tests for TB: CAD4TB, a digital chest X-ray analysis software, and point-of-care C-reactive protein assay (POC-CRP). The accuracy of these tests can be improved by stratifying thresholds based on patient characteristics, such as HIV status, history of TB, and TB symptoms. To evaluate the effectiveness and cost-effectiveness of these tests, the TB TRIAGE+ TRIAL is being conducted. This trial will compare two screening/triage approaches: CAD4TB screening alone versus CAD4TB screening with an adjusted POC-CRP triage algorithm. The results will be confirmed with Xpert MTB/RIF Ultra testing.

Nested within this study is the Advanced HIV Disease screen protocol, aimed at identifying advanced HIV disease, defined as CD4 count < 200 cells/mm3 of WHO stage 3 or 4, and screening for TB and other infections in people living with HIV. The first step of this protocol involves identifying advanced HIV disease using a CD4 test. A disposable point-of-care test, Omega VISITECT CD4, is being used that allows for visual interpretation of CD4 results providing a semi-quantitative result of CD4 above or below 200. If advanced HIV disease is detected, screening for TB lipoarabinomannan (TB LAM) and cryptococcal antigen (CrAg) is performed using point-of-care urine TB LAM and CrAg lateral flow assays, with patient management based on results. In all persons living with HIV and with symptoms of TB, a molecular diagnostic test for TB along with TB LAM is performed, regardless of CD4 count. This study seeks to assess whether the Advanced HIV Disease care package, including same-day initiation of ART, TPT and cotrimoxazole prophylaxis, can be implemented during the community-based TB TRIAGE+ health campaign.

The study was successful in engaging community stakeholders to agree on appropriate setup points for mobile clinic services, leading to high participation and uptake. The availability of X-ray imaging was a significant draw for participants, as it is not typically available at primary healthcare facilities and is perceived as a special and expensive form of imaging. The integration of various screening tests, including blood pressure, HbA1C, HIV testing, and TB screening, into one session with a single nurse was well received by participants, compared to studies that only offered testing for HIV or TB.

The point-of-care (POC) approach was beneficial from a study perspective, as results were obtained quickly without losing participants. Participants appreciated

the efficiency of POC compared to the traditional system offered by the Department of Health, where a follow-up appointment was required 7 to 14 days after sample collection. The absence of storage facilities at the clinic meant that certain samples could not be collected if the courier had already visited for the day, and hard copies of results were often lost or not returned, leading to the need for retesting.

The flow of multiple rapid tests was carefully considered to minimize blood draws and wait times. For example, the Visitect test, which takes 40 minutes, was prioritized as one of the first procedures to be performed.

Several limitations to the use of point of care devices were encountered during implementation of the community health campaign. One of the key issues was the requirement of electricity for the X-Ray machine, which relied on a generator. This was problematic during times of instability, such as during the riots of 2022 when diesel for the generator was not readily available and the service had to be shut down. Additionally, the switch from the Afinion CRP device to the Gates funded Lumira Dx platform, which was designed to be more robust for in-field use, resulted in increased error rates in extreme temperatures. This highlights the limitations of using these platforms in community settings, as was previously noted. Finally, while community screening with point of care devices was effective in identifying patients with illnesses, integrating them into existing health services proved to be more challenging. The increasing prevalence of chronic illnesses, such as obesity, mental health issues, and substance abuse disorders, identified through community screening also posed a significant threat of overwhelming an already burdened health system. Finally, the use of AI diagnostics in low-resource settings has both potential benefits, along with significant risks and ethical dilemmas associated with the use of AI in these contexts. These include concerns around bias, overreliance, and data privacy, as well as the potential for data colonialism and exploitation.

To address these concerns, it is crucial to develop responsible AI practices that prioritize transparency, accountability, and the ethical implications of this technology. This includes the use of edge computing to preserve data privacy, and the recognition of a need for a new data governance model that prioritizes trust, solidarity, accountability, and participation. It is important to ensure that the responsible use of AI is prioritized and that the potential risks and limitations of AI are clearly communicated to those using it. Ultimately, the responsible use of AI in low-resource settings requires a collaborative and multidisciplinary approach that prioritizes the ethical and social implications of this technology.

In conducting the study, several lessons are being learnt and considerations for future steps appearing. Firstly, there is a discrepancy between current legislation and regulatory requirements and the services the study intends to offer. For instance, the requirement for a nurse with a dispensing license to dispense ART and for the X-Ray machine to be in a lead-lined room present challenges for implementation in community settings. Secondly, we see an opportunity to support individuals who are screened negative for various illnesses, such as

offering health information or resources for risk reduction, contraception, or PrEP. Additionally, the GeneXpert test has been found to be challenging to perform in the field due to the long wait time, and we are considering sharing results by SMS or phone call instead. Furthermore, the study shows the demand for accessible, local, and efficient services with immediate action and consideration could be given to expanding the current POC offering.

Finally, we note that the use of multiple rapid tests, each on its own platform and requiring unique reagents, could be streamlined and integrated into fewer platforms. For TB specifically, there is a need for novel tests that do not require sputum and alternative methods to GeneXpert for confirmation.

Some current and upcoming outputs:

Gils, T., Lynen, L., Muhairwe, J., Mashaete, K., Lejone, T. I., Joseph, P., Ngubane, T., Keter, A. K., Reither, K., & van Heerden, A. (2022). Feasibility of implementing the advanced HIV disease care package as part of community-based HIV/TB activities: a mixed-methods study protocol. BMJ Open, 12(2), e057291.

Kipyegon Keter, A., Lynen, L., van Heerden, A., Goetghebeur, E., & Jacobs, B. K. M. (2022). Implications of covariate induced test dependence on the diagnostic accuracy of latent class analysis in pulmonary tuberculosis. Journal of Clinical Tuberculosis and Other Mycobacterial Diseases, 100331.

COVID-19 Screening in Low Resource Settings using Artificial Intelligence for Chest Radiographs and Point-of-Care Blood Tests (submitted) . Keelin Murphy, Josephine Muhairwe, Steven Schalekamp, Bram van Ginneken1, Irene Ayakaka, Kamele Mashaete, Bulemba Katende, Alastair van Heerden, Shannon Brosman, Thandanani Madonsela, Lucia Gonzalez Fernandez, Aita Signorell6, Moniek Bresser, Klaus Reither, Tracy R. Glass

Biography

Alastair van Heerden is a research director in the HSRC's Human and Social Capabilities research division and leads the HSRC Sweetwaters Centre for Community-based Research. He holds a PhD in Public Health from the University of the Witwatersrand (2013) where he also holds an honorary Associate Professor appointment within the Department of Clinical Medicine. Van Heerden specialises in community-based intervention trials, digital and mobile health, and information and communications technology for development (ICT4D).

Alastair has over 10 years' experience conducting clinical, behavioural and community-based research throughout East and Southern Africa, Nepal and Brazil. He has an interdisciplinary focus to his research, which combines interests in technology for development and public health. These interests informed his PhD, which focused on pervasive computing in health; particularly, how to harness inexpensive mobile technology to support health research in low- resource settings. He has been responsible for the implementation of several multi-year grants including work funded by the NIH (1R01MH077553, 1R01HD055137, 1R01MH105534-01A1), Gates (OPP1134599) and the European and Developing Countries Clinical Trials Partnership (RIA2018D-2498).

Central to these studies was his desire to find community-based solutions to the challenges of centralised primary health care. Most recently he has worked to better understand how the digital sensing of behaviour can be used to support health interventions among young women with post-natal depression (episodic audio and proximity beacons, OPP1189927), healthy adolescents in Brazil (accelerometry, GPS and screen time, FF.1920.1.61), depressed adolescents in South Africa and Uganda (behavioural activation-based serious games, 1710HQ001/VW1) and gestational diabetes in obese pregnant women (continuous glucose sensors and machine- learning models designed to support understanding of activities of daily living, ACC2018003).

Alastair is a National Research Foundation C2-rated researcher. He has published 61 scientific articles in local and international peer-reviewed academic journals, 8 research reports, and 2 book chapters. He has also presented more than 50 papers and posters at local and international conferences. He is part of the editorial advisory board for the Global Health & Infectious Disease section at Heliyon and an ad-hoc reviewer for the Journal of Medical Internet Research, Journal of the International Aids Society, and Social Science and Medicine.

Session 4: Industrial Perspectives

1. The SAMBA Journey

Dr Helen Lee (Session Chair)

Biography

Helen Lee received her master's and PhD from University of Oxford and Cornell University respectively. She is a researcher/entrepreneur with a lifelong dedication to medical diagnostics. She withdrew from a successful career in industry at Abbott Laboratories, Chicago as head of Molecular Diagnostics Business Unit, to focus on the pursuit of advanced technologies specifically suited for resource-strapped regions.

After creating the Diagnostics Development Unit at Cambridge University, Dr Lee founded – together with a group of like-minded colleagues – a spinout company called Diagnostics for the Real World Ltd, with the single purposes of delivering much-needed high performance yet simple and robust molecular tests to the developing world. She chaired the Diagnostic Steering Committee at the World Health Organization and among the many awards received, she is the recipient of the prestigious Lord Lloyd Kilgerran Award, the British Female Inventor in Industry Award, the European Women of Achievement Award and the Asian Women of Achievement Award. In 2016, she was a winner of the European Inventor's award.

2. Engineering Point-of-care Diagnostics in LMICs; Opportunities and challenges

Dr Laud Anthony Basing

Introduction

There are approximately 12 million avoidable deaths per year in Africa. These are deaths that could easily have been prevented if they were detected early. This is because the laboratory infrastructure to detect these diseases is often non-existent in several communities. Point-of-Care tests (PoCs) offer a viable alternative as they are easily deployable and relatively more affordable. PoCs are however not available for many diseases especially those that affect the poor and vulnerable in Africa. Coupled with issues of supply chain and cost, there has been an enhanced call for local production of diagnostics.

Yaws is a neglected tropical disease, considered a disease of poverty caused by Treponema pallidum subsp. pertenue (TPE). It affects people living in very deprived hard-to-reach rural communities. Ghana is one on the most endemic countries in the world, but the disease is prevalent in very rural communities across the country. Infection with yaws, if untreated, can lead to gross deformities and disabilities. Yaws can be treated effectively with a single dose of azithromycin and the World Health Organization has earmarked yaws for eradication by the year 2030. The eradication of yaws, however, is constrained by the lack of rapid, accurate diagnosis. Until a few years ago, samples had to be taken outside Ghana for testing before treatment could be administered. This could take anytime from 3 weeks to several months.

Overview of projects

There are two main projects embarked by the company to solve the problems stated above: the Incas manufacturing project as well as the yawskit project.

The manufacturing project involves the local manufacture of easy-to-use point-of-care tests: pregnancy test, test for Hepatitis B, an antibody test for typhoid (IgM/IgG), a 10-in-1 urine panel for Drugs of Abuse (Marijuana, Opiates, Barbiturates, Cocaine, Benzodiazepine, Tramadol, Amphetamine, Nicotine, Morphine and Tricyclic antidepressants), a urine test for alcohol abuse, a test for Malaria (Pf/Pan), a test for HIV 1&2, a test for ovulation, a 3-in-1 test for vaginal infections, a test for syphilis, a 2-in -1 test for gonorrhoea and chlamydia and a test for Covid-19.

The yawskit is based on Loop Mediated Isothermal Amplification. The reagents are lyophilized into a tube and only requires the addition of the sample. The sample is heated at 360^{o}C for 30 minutes and then visual detection of yaws is achieved by the use of a lateral flow test strip. The yawskit, for use by semi-skilled community health workers, can provide results in 45 minutes versus up to several weeks for real time PCR lab results.

Key issues

Developing and manufacturing Point-of-Care diagnostics in Africa comes with several challenges including problems with supply chain, the business environment, regulatory challenges, financial challenges including an unstable currency as well as a general preference for imports.

Main Outputs of projects

The manufacturing project has generated 12 products on the market, 37 employees and 56 distributors across the country. The YawsKit was clinically evaluated between 2020 and 2022 in three districts in Ghana. We found a sensitivity of 91.75% and a specificity of 97%.

Lessons learnt

Despite the seemingly enormous challenges with developing and manufacturing diagnostics in Africa, these challenges are not unsurmountable. An assessment and knowledge of the business environment coupled with careful planning is key to overcoming these challenges.

Next steps

The local manufacturing project is being expanded to two other countries (Nigeria and Kenya) whilst products from Ghana would be exported to 5 other African Countries, mostly Francophone West Africa. The next step for the YawsKit is to go through regulatory approvals for manufacture and commercialization.

Biography

Laud Anthony Basing is a Scientist, Engineer, Innovator and Entrepreneur. He is the CEO and Founder of Incas diagnostics, a social enterprise in Ghana, which seeks to save lives through the design and production of low-cost, easy-to-use, point-of-care diagnostic test kits designed specifically for Africa. He is also the Executive Director of Incas Impact Foundation, a foundation which offers mentorship, training and capacity building for Ghanaian youth.

Laud Anthony is passionate about research, and with a background in both Microbiology and Biomedical Engineering, his research interest has been in developing simple tests for infectious diseases that largely impact women and children in Africa. He has several years of research experience with international collaborations. He worked with the University of Liverpool and researchers from 13 countries from 2009 to 2013 on a project on the effect of climate change on health outcomes. He worked with the World Health Organization in Ghana and Papua New Guinea on yaws eradication from 2015 to 2016 and worked with the Weldon School of Biomedical Engineering, Purdue University in the United States to develop low-cost, mobile-enabled test devices for HIV and Yaws. He currently leads an European and Developing Countries Clinical Trials Partnership (EDCTP) funded program to evaluate a rapid diagnostics for yaws in Ghana, Ivory Coast and Cameroon. He has

made poster and oral presentations in Nigeria, Mali, Spain, South Africa, China, Cape Verde, Kenya and the US.

Laud Anthony Basing is a 2016 Mandela Washington Fellow in the Business and Entrepreneurship track and was previously the Chairman of the Linkages Committee of the West and Central African Regional Advisory Board for the fellowship. He is a member of American Society for Microbiology (ASM)'s Young Leaders Circle, and the former ASM Young Ambassador to Ghana. He is the former Vice Curator of the Kumasi hub of the Global Shapers Community, a global network of young people driving dialogue, action and change, a former

President of the Young African Leaders' Network-Ghana and a member of the Alliance for Young entrepreneurs Ghana. On the professional front in Medical Laboratory Practice, he is a former regional executive of the Ghana Association of Medical Laboratory Scientists (GAMLS) having been the Secretary of the Komfo Anokye Teaching Hospital (KATH) Chapter, Ashanti Regional Secretary, Ashanti Regional Financial Secretary and Ashanti Regional Vice Chairman.

Laud Anthony is the first Ghanaian to have been nominated for the Innovation Prize for Africa, a prestigious award aimed at strengthening African innovation ecosystems through supporting a culture of innovation and competitiveness, whilst spurring growth of innovative, market-driven African solutions to African challenges. He was named one of the 50 most influential young Ghanaians in 2017 and a 2017 Emerging Leaders under 40 winner in the health and wellness category in Ghana. Laud won first place in the social innovation track of the 2018 Burton Morgan Business Model Competition in Purdue University and Second place in the 2017 Shurz Innovation Challenge for developing a urine-based Point of Care Diagnostic Kit for Sexually transmitted Diseases.

In March 2019, Laud was named one of the top 30 innovators in health in Africa in the World Health Organization's Africa Innovation Challenge in 2019 for developing a molecular based rapid test kit for the neglected tropical disease yaws. In March of 2020, Laud led a team from Ghana, Senegal, Cameroon, South Africa and Nigeria to win WHO's COVID-19 Hackathon with CoviTTrads a Covid19 testing and tracking platform. In April 2020, Laud led a team of scientists from Incas Diagnostics to collaborate with KNUST to develop a rapid test kit for covid19 and in May 2020, he won Africa.com's Brilliant African Innovations Against COVID-19.

3. Overview of the Nanapore portfolio in diagnostics and a deep dive into the work on TB

Dr Emma Stanton & Prof. Justin O'Grady

Oxford Nanopore Technologies plc was founded in 2005 and currently employs approximately 1,000 people. We have developed a new generation DNA/RNA sequencing technology. It is the only sequencing technology that offers real-time analysis (for rapid turnaround time), in fully scalable formats from pocket to population scale, that can analyse native DNA or RNA and sequence any length of fragment to achieve short to ultra-long read lengths. This technology has been used in many different settings, from the international space station to the Arctic, and is perfectly suited for diagnostics in LMICs due to its low cost and high portability.

In this talk, we will discuss how Oxford Nanopore Diagnostics are exploiting the unique features of nanopore sequencing to improve diagnosis/prognosis in cancer, human genetics and infection.

We will then focus in detail on the application of a rapid (~4hr) targeted nanopore sequencing assay for the detection and characterisation of drug resistance in tuberculosis and how we are driving the clinical implementation of this assay.

Biographies

Emma Stanton joined Oxford Nanopore in 2020 as Clinical Vice President. She is also Head of Oxford Nanopore Diagnostics (OND). In this role, she supports growth in healthcare applications using nanopore-based sequencing. In 2020, Emma was Director for Supplies and Innovation as part of the British government's NHS Test and Trace response to COVID-19. Prior to this, Emma was CEO of Four Eyes Insight (2018-2020), Chief Partnership Officer for Beacon Health Options (USA 2015-2017) and CEO of Beacon in the UK (2011-2016).

Emma has also been a Commonwealth Fund Harkness Fellow in Healthcare Policy and Practice and a Senior Associate at the Institute for Strategy and Competitiveness, both at Harvard University, USA. Prior to this, Emma was a practicing clinician in the National Health Service (NHS). Emma holds an Executive MBA from Imperial College London, a MRCPsych from the Royal College of Psychiatrists and a Bachelor of Medicine from Southampton University.

Justin O'Grady gained his BSc, MSc and PhD in microbiology and infectious diseases at the National University of Ireland Galway (NUIG). He remained at NUIG for his first post-doc, focussing on foodborne pathogens. This was followed by a two-year stint in industry (Beckman Coulter) developing real-time PCR based tests for infectious diseases. Prof O'Grady then returned to academia, taking a post-doc position at University College London on TB diagnostics.

In January 2013 he was appointed Assistant Professor in Medical Microbiology at the University of East Anglia (Norwich, UK), was promoted to Associate Professor in August 2016 and promoted to Professor in January 2021. He then joined Oxford

Nanopore Technologies as Senior Director of Translational Applications in June 2021. His research continues to focus on the development of rapid diagnostic tests, to maximise community and patient benefit.

5 & 6: Clinical Perspectives

1. Session Overview

Prof. Chrystalina Antoniades

Low- and middle-income countries (LMICs) face significant challenges in *diagnosing* and managing neurological diseases[1], due to factors including limited access to healthcare services, inadequate diagnostic facilities, and a shortage of trained healthcare professionals.

In LMICs, the burden of neurological diseases is increasing, with stroke, epilepsy, Parkinson's and dementia[2] being some of the most common conditions. One of the main challenges in diagnosing neurological diseases in LMICs is the lack of diagnostic tools and expertise. This can lead to delayed or missed diagnoses, resulting in further complications and poor outcomes. Many LMICs have a severe shortage of neurologists which can result in a lack of specialized care for patients with neurological conditions, further contributing to poor outcomes[3].

Many LMICs do not have sufficient access to advanced imaging technologies, such as magnetic resonance imaging or computed tomography scans, which are essential in diagnosing conditions such as stroke and brain tumours. Another significant challenge is the cost of diagnostic tests and treatment. Many people in LMICs cannot afford to pay for expensive tests or medications, and this may be a further cause of delayed diagnosis and inadequate treatment.

It is essential to improve access to healthcare services, including diagnostic facilities and trained healthcare professionals. Governments and international organizations can invest in building or upgrading healthcare infrastructure, providing training for healthcare professionals, and implementing public health programs to increase awareness of neurological diseases. In addition, recent solutions that have come about such as telemedicine and mobile health (mHealth) technologies can help overcome barriers to healthcare access in LMICs, allowing remote consultation and diagnosis, as well as monitoring and management of neurological conditions.

Overall, improving the diagnosis and management of neurological diseases in LMICs requires a concerted effort from all stakeholders, including governments, international organizations, healthcare professionals, and patients and their families.

During this talk I will give an overview of this clinical perspectives session and I will briefly focus on Parkinson's disease. The diagnosis of Parkinson's disease is primarily based on clinical symptoms, as there are no specific laboratory tests or readily available imaging studies that can accurately diagnose the condition. In LMICs access to specialized healthcare and diagnostic tools can be limited, which makes the diagnosis of Parkinson's disease more challenging.

However, there are still several ways that healthcare providers in these countries can diagnose the condition. In addition to using the standardised UK Parkinson's Disease Society Brain Bank Clinical Diagnostic Criteria, complementary tools such as wearable

devices that can track movement and provide objective data might be incorporated. Current work within my research group is focusing on validating a new app using aniPhone and Apple watch as a means of remote and home monitoring in a Parkinsonian population in the United Kingdom.

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Biography

Chrystalina Antoniades is an Associate Professor of Neuroscience in the Nuffield Department of Clinical Neurosciences, and head of the NeuroMetrology Lab, University of Oxford.

Chrystalina's research team is developing novel ways of accurately measuring various functions in patients with neurological disorders, such as Parkinson's disease and dementia. Many medical conditions can be rapidly and accurately quantified using standard equipment. For example, the severity of asthma can be measured by the rate of airflow rate to the lungs, and heart disease can be detected according to the degree of narrowing of arteries. However, many brain diseases, including Parkinson's Disease (PD) and Progressive Supranuclear Palsy (PSP - a type of atypical Parkinsonism), are measured using a clinical rating scale, a system of points assigned by an observer based on their impression of the person's condition. Such scales are subjective, i.e. two different people assessing the same patient may not score the patient equally, and they are also nonlinear, meaning that for example the difference between a score of 30 and 40 may not be the same as the difference between a score of 20 and 30. Such rating scales make analysis of change in a patient's condition over time difficult and therefore not ideal for use in clinical trials of new drugs. As a consequence, clinical trials may unnecessarily consume a large amount of resource before an outcome becomes apparent.

The NeuroMetrology Lab is developing new approaches to precisely measure abnormalities of movement and its control using neurophysiological biomarkers. Its eventual aim is to replace clinical rating scales in both scientific research and everyday practice, with reliable and objective numerical measures.

Chrystalina is very active in the public engagement arena, something she is passionate about. She set up and leads the Art and Neurosciences project for the Medical Sciences Division, and more recently started a new project "Picturing Parkinson's".

2. Development of Highly Reliable Point of Care Diagnostics for Africa

Dr Jesse Gitaka

Infectious, poverty related diseases, and adverse maternal and newborn outcomes continue to be major health burdens in Africa. Malaria, HIV, TB and neglected tropical diseases have ravaged most health systems in Africa. Highly reliable, field-deployable point of care diagnostics are needed to enable detection of infectious reservoirs to effectively break transmission towards elimination of these communicable diseases. However, Africa has been lagging behind in designing and developing home-grown solutions.

Our group, Gitakalab, (www.gitakalab.com) works on developing, prototyping and implementing point of care diagnostic tests for infectious diseases, and those that address maternal and newborn health. Here, we shall discuss 2 projects that highlight our work. In the first, we have developed a method for detecting Streptococcus agalactiae, also known as Group B Streptococcus (GBS), in just 20 minutes. Our approach involves using on-chip magnetic isolation of GBS, which is achieved through immiscible filtration assisted by surface tension (IFAST). Once isolated, we detect the GBS using an adenosine triphosphate (ATP) bioluminescence assay. We tested the effectiveness of our method by spiking artificial urine samples with GBS cells, and were able to isolate up to 80% of the GBS cells with a linear response of bioluminescence signals from isolated cells ranging from 2.3 × 102 to 9.1 × 105 CFU mL^{-1}. This demonstrates the potential for our approach to be used for point-of-care detection of pathogenic bacteria in urine samples from pregnant women. We also faced practical challenges when testing our protocol with urine samples in Kenya, including delays in acquisition of reagents due to customs processes. However, the excellent participation by different stakeholders in the project was very commendable.

In the second project, genome-mining approaches were used to identify identical multi-repeat sequences (IMRS) distributed throughout the genomes of Neisseria gonorrhoea (NG) and Chlamydia trachomatis (CT) to design primer pairs that target numerous regions. Genomic DNA from bio-banked NG positive urethral swabs and CT isolates was 10-fold serially diluted and used as DNA template for PCR reactions using the IMRS primers. The IMRS PCR assay for NG was found to be >1052 times more sensitive than conventional 16s RNA PCR, with a lower limit of detection of 0.006 pg/µl, and was comparable in detecting cultured NG from infected patients. The IMRS PCR assay for CT was also more sensitive than 16s rRNA PCR, with an analytical sensitivity of 0.0095 pg/µl, representing >453 times better sensitivity. Both assays were confirmed using Sanger sequencing. Algorithm-based *de novo* genome mining of IMRSs as amplification primers can serve as a novel platform technology for developing ultrasensitive diagnostics for NG and CT genomes, and potentially a wide range of infectious pathogens. This concept has the potential to be implemented in miniaturized, point-of-care, isothermal, microfluidic platforms and laboratory-on-a-chip diagnostic devices.

Both projects highlight the potential for in-continent development of highly sensitive assays and tests despite several challenges. Increasing desire to build biotechnological

capacities for development and manufacturing, especially following the COVID 19 pandemic, provide a huge opportunity to spur critical value chains in point of care tests pipelines. Indeed, it is on this background that we have in 2022 worked together with Prof. Nicole Pamme of Stockholm University to found the AfyaDx Network aimed at boosting collaborative networks between European and African researchers working on Point of Care tests development and implementation. Holding monthly webinars via Zoom, we held 10 meetings bringing together > 200 unique participants and >24 speakers discussing various topics including assay development, manufacturing, field evaluations, policy and economics of the value chains. We anticipate that this effort will lead to future linkages for greater productivity and impact.

AfyaDx Network LinkedIn page: https://www.linkedin.com/company/afyadx-network/

Biography

Jesse Gitaka MD, MTM, PhD; is a Kenyan physician scientist with extensive experience, spanning clinical practice and trials, molecular biology and epidemiology of infectious diseases and implementation science. Additionally, he is a senior lecturer at Mount Kenya University, Kenya where he is the founding director for the Centre for Malaria Elimination and team leader at Gitakalab (https://gitakalab.com/). He is a visiting associate Professor at the Institute of Tropical Medicine, Nagasaki University, Japan, an affiliate of the African Academy of Sciences, a Future Leaders-African Independent Researchers (FLAIR) fellow and a Next Einstein Fellow.

Jesse's work is mainly focussed on infectious diseases and maternal health, developing highly reliable diagnostic assays, molecular epidemiology and host pathogen interactions. He develops isothermal nucleic acid analysis techniques for diagnosis of CuSTIs (curable sexually transmitted infections) and malaria in pregnancy using lab-on-a-chip devices, fibre mats and smartphone readouts to enable on-site pathogen analysis in resource-limited settings for prompt treatment alleviating prematurity, stillbirths and neonatal deaths. Additionally, he works on surveillance for bacterial and malaria drug resistance and virulence genes, employing a network of health facilities across Kenya and the region. Lastly, he studies innovative strategies to alleviate poor maternal and new-born outcomes.

3. Enhancing Patient Care through Pathology Lead Strategic Activation of Point-of-Care Testing

Dr Daniel Maina

Background

Aga Khan University Hospital, Nairobi (AKUHN) is a private, not-for-profit institution which was established in 1958 and upgraded to a University teaching hospital in 2005. It provides tertiary and secondary level health care services to the residents of the capital city, surrounding counties and the wider East African region.

The hospital has JCIA accreditation (2013) while the main laboratory has both ISO 15189 (SANAS 2011) and CAP (2019) accreditations. Whereas JCIA and CAP have clauses on PoCT and audit the service, ISO 15189 did not include PoCT but this has changed with the updated standard. [SANAS- South African National Accreditation System, JCIA- Joint Commission International Accreditation, CAP- College of American Pathologists]

POCT Program Genesis (2012)

POCT existed without a framework to guide its use. Decisions regarding testing were left to individual user departments with none or little oversight by laboratory medicine professionals. Concerns regarding PoCT were raised in an audit in preparation for hospital accreditation by JCIA (2010). Laboratory testing in critical areas was found wanting and the Pathology Department was mandated to take charge.

In 2012, there were 18 PoCT locations in the hospital with 27 pieces of equipment including BGAs, glucometers, coagulometers and a cardiac reader. Efforts to formally institute a PoCT program did not succeed until 2017, with buy-in from senior leadership. POCT committee members were officially appointed by the Medical Director, with regular meetings held in which pertinent issues affecting POCT services were deliberated. A new POCT policy was drafted and approved.

Connectivity (2018)

PoCT sites within hospital had increased to 33 with close to 100,000 tests annually. Over 500 personnel were involved in direct patient testing using POCT devices. A large amount of documentation was required on the following topics:

- Training
- Competence & recertification
- QC data
- Device maintenance charts
- Inventory and stocks

- Patient results

All data were being captured and reviewed manually which was not thorough and efficient. The PoCT coordinator had to make many rounds to cover all the sites. Several gaps were exposed during audits: inconsistent and inadequate documentation of QC, lack of management review of QC data, training and competency records of testing personnel lacking or incomplete, staff credentialing, no documentation of critical values. For example, glucometers (SMBG) had been deployed without validation, and the inventory was not updated when replacements were made.

Due to the above challenges a decision was made to digitise PoCT. Analogue glucometers were replaced with digital meters with enhanced functionalities designed for hospital use. Use of middleware from the vendors enabled a centralized command structure to oversee PoCT activities.

This allowed all the processes in PoCT to have a digital presence, except for the transmission of the results to LIS since the latter was outdated. Bidirectional communication with all PoCT equipment has, however, been effected since December 2022 with implementation of a new LIS with enhanced features.

Success

Implementation of upgraded PoCT program was recognised by the Univants of Healthcare Excellence Awards with a three-star distinction.

Challenges

None of the vendors in the country had ever dealt with digital meters and it took a while to procure them. It took time, continuous training and resources to fully implement digitization. Testing personnel were initially reluctant to adopt the technology as it called for more accountability on their part, but this has since changed to appreciation.

Output

1. Patient:

    - Increased safety
    - A 5-fold reduction in medical errors
    - Elimination of mismatched patient results
    - Mitigation of pre-analytic confounders (20% reduction)
    - Enhanced compliance (3% to 100%) of routine quality control (QC)
    - Response to, and actions associated with, mandated critical alerts increased by 70% (30% to 100%)

2. Clinician:

    - Increased confidence in the accuracy of results generated in PoCT

3. Hospital administration:

    - Mitigated lost revenue; the revenue from PoCT increased by 25 %, through improved data capture and associated documentation/billing process.

Lessons learnt

Technology when well applied can enhnce patient care through improved efficiency and coordinated monitoring of PoCT. Hospital administration buy-in and commitment to avail resources to support PoCT and interdepartmental collaboration are key to a successful program. Accreditation of PoCT can be a motivation to improve the service. The plan is to expand the PoCT menu now that the basic infrastructure is largely in place.

Biography

Daniel Maina is Consultant Clinical Pathologist & Assistant Professor at the Aga Khan University Hospital Nairobi Kenya, Fellow of the College of Pathologists East, Central and Southern Africa (FCPATH ECSA). He has worked in several medical institutions within Kenya, and has been affiliated to the Aga Khan University Hospital since 2006, currently stationed in the chemical pathology laboratory where he is engaged in service provision, research. He has been the Chair of the hospital Point of Care Testing (POCT) Committee since 2017 as well as a member of the African Federation of Clinical Chemistry (AFCC) POCT committee. The hospital PoCT program received a certificate of distinction in the Univants of Healthcare Excellence awards in 2020 for initiatives that reduced medical errors and enhanced quality of care.

He has actively been involved in the accreditation process of the AKUHN laboratory by SANAS (ISO 15189) and the College of American Pathologists (CAP). His research interests are in the areas of metabolic & molecular medicine, and Point of Care diagnostics.

4. Malaria diagnostic resistance in routine case detection in a primary healthcare facility in Kenya

Dr Isabella Oyier

Dorcas Okanda[1], Leonard Ndwiga[1], Victor Osoti[1], Nicole Achieng[1], Juliana Wambua[1], Caroline Ngetsa[1], Peter Lubell-Doughtie[2], Anuraj Shankar[3], Philip Bejon[1,3], **Lynette Isabella Ochola-Oyier**[1,4]

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There is a growing concern for malaria control in the Horn of Africa region due to the spread and rise in the frequency of Plasmodium falciparum histidine-rich Protein (hrp) 2 and 3 deletions. Parasites containing these gene deletions escape detection by the major PfHRP2-based rapid diagnostic test, thus reducing the management of clinical cases. In this study, malaria rapid diagnostic tests (RDTs), microscopy and quantitative PCR (qPCR) were used concurrently to support malaria diagnosis in a primary healthcare (PHC) facility in a moderate-high malaria transmission area. Subsequently, the presence of Pfhrp2/3 deletions was examined in the uncomplicated malaria patients in Kilifi County.

345 samples were collected from the PHC facility in 2019/2020 during routine malaria care for patients attending this primary health care facility. The CarestartTM RDT, an RDTScan for automated malaria RDT detection, qPCR and microscopy were used to test for malaria. Microscopy is the gold standard assay for malaria detection; there was >90% sensitivity between microscopy and Carestart and RDTScan RDTs. In contrast, qPCR vs microscopy performed slightly better (92%) when compared to both the routine and mobile-read RDTs (~88%). In addition, including molecular analyses of the parasites from the qPCR, Carestart and microscopy positive samples, there were no Pfhrp2 and Pfhrp3 negative parasites in the 11 RDT negative and microscopy positive discordant samples.

These findings revealed consistent results within the diagnostic tools for the sensitive detection of malaria infections. Furthermore, there is currently a low prevalence of Pfhrp2 and Pfhrp3 deletions in the health facility in Kilifi. However, routine monitoring in other primary health care facilities across the different malaria endemicities in Kenya is urgently required to ensure appropriate use of malaria RDTs. New tools are therefore required to support malaria diagnosis in malaria endemic regions.

Biography

Isabella Oyier is an Associate Professor and the Head of the Biosciences Department at the KEMRI-Wellcome Trust Research Programme (KWTRP). She is currently a Calestous Juma Fellow, funded by the Bill & Melinda Gates Foundation since 2021, to

integrate malaria molecular epidemiology into routine surveillance in Kenya, a project that partners with the Division of National Malaria Programme (DNMP) to implement malaria molecular surveillance activities. During the COVID-19 pandemic, she led testing efforts and co- ordinated the regional genomic surveillance in collaboration with Africa CDC and WHO-Afro. With recent funding from Wellcome, she leads a project to continue work nationally and regionally on COVID-19; to establish a platform for immunological surveillance to identify and report, in near real-time, on the immune escape potential of newly emergent SARS-CoV-2 variants.

She previously was awarded a Wellcome Intermediate Fellowship and was a Visiting Lecturer at the Centre for Biotechnology and Bioinformatics (CEBIB), University of Nairobi, in 2011- 2016. She has been and is a member of several technical working groups on genomic surveillance, including the DNMP Operational Research committee of experts and Africa CDC malaria genomic surveillance advisory group. She has over 50 publications in peer-reviewed journals.

Her research interests are in Plasmodium falciparum malaria molecular epidemiology, focusing on the spatial and temporal use of molecular tools to: 1) examine genetic variation in merozoite antigens that are potential candidates for blood stage vaccines and its impact on naturally acquired immunity; 2) define complexity of infection while examining the impact of interventions or changes in malaria epidemiology; 3) distinguish persistent infections and reinfections in both therapeutic efficacy studies and in longitudinal follow up of asymptomatic individuals; and 4) monitor drug resistance molecular markers.

5. Using Self-Supervised Feature Learning to improve the use of Pulse Oximeter Signals to Predict Paediatric Hospitalization

Mr Paul Mwaniki

Paul Mwaniki[1], Timothy Kamanu[2], René Eijkemans[3], Samuel Akech[1], Dustin Dunsmuir[4], Mark J Ansermino[5]

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The World Health Organization recommends the use of Emergency Triage and Treatment (ETAT) guidelines for triaging sick children in low- and middle-income settings. However, inadequate staffing levels and a lack of adequate training have hindered the effective utilization of the guidelines. Moreover, ETAT guidelines rely on the assessment of clinical signs and symptoms that are subjective.

In this study, we sought to develop machine learning models that could use pulse oximeters to triage sick children in low-income settings. Pulse oximeters are widely available in routine clinical settings and are used to measure oxygen saturation and heart rate. However, the underlying Photoplethysmography (PPG) signals from pulse oximeters contain information on respiratory and cardiovascular function that could be used to predict various medical conditions or pathophysiological states. In this study, hospitalization was used as a proxy for severity of illnesses.

Project description

The study was conducted in the outpatient department of a public hospital in Nairobi. Demographic and clinical information was collected from children recruited into the study. PPG signals were collected using a pulse oximeter that was connected to an Android tablet. Hospitalization decisions were made by the facility physicians who were not part of the study and had no access to the study data. Self-supervised learning (SSL) models using contrastive learning were used to extract features from raw PPG waveforms. The extracted features were used to predict hospitalization using logistic regression. Additional logistic regression models were fitted using extracted features and clinical features identified in previous analyses. In addition, the weights of the SSL models were used to initialize end-to-end deep learning models for predicting hospitalization using raw PPG signals. The utility of large unlabelled datasets in improving the SSL models was evaluated by including PPG signals sourced from a study conducted in a similar setting in Uganda.

Key issues

The size augmentation techniques would be appropriate for PPG signals. Lasso and ridge regression techniques were not sufficient in preventing over-fitting in the logistic regression models fitted using higher-order interactions of the extracted features.

Results

Logistic regression models were more predictive of hospitalization when trained on features extracted using labelled PPG signals only, compared to SSL models trained on both labelled and unlabelled signals (AUC 0.83 vs 0.80). However, features extracted using the SSL model trained on both labelled and unlabelled PPG signals were more predictive of hospitalization when concatenated with clinical features (AUC 0.89 vs 0.87). The end-to-end deep learning model had an AUC of 0.80 when initialized using the SSL model trained on all PPG signals, 0.77 when initialized using SSL trained on labelled data only, and 0.73 when initialized randomly.

Lessons learnt and future plans

Future work will consider Bayesian neural networks for end-to-end deep learning models to prevent over-fitting and estimate the level of uncertainty in the predictions. Additional research is required to determine optimal risk cut-offs for triggering action because the implications of false positives and false negatives are not equal.

Biography

Paul Mwaniki is the KEMRI-Wellcome Trust Research Programme (Nairobi) lead statistician and a final year PhD student at the University of Nairobi. His doctoral research investigates using large unlabeled data sets to improve Machine Learning (predictive) models developed from smaller labeled data sets in low-income settings. Paul has an MSc in Medical Statistics from the London School of Hygiene and Tropical Medicine and a BSc in Applied Statistics with Information Technology from Maseno University (Kenya). Paul is interested in applying data science and Machine learning to improve healthcare delivery in low-income settings. He is currently working on machine learning models that could identify severely ill children to improve triage in hospitals. In addition, Paul has evaluated the utility of audit and feedback in improving the adoption of paediatric clinical guidelines using data from medical records.

6. Scaling Digital Transformation: The eyeSmart EMR experience at LVPEI

Dr Vipin Das

According to the WHO, vision impairment poses an enormous global financial burden with the annual global costs of productivity losses associated with vision impairment estimated to be $411 billion. The leading causes of vision impairment and blindness are uncorrected refractive errors and cataracts. Globally, at least 2.2 billion people have a near or distance vision impairment. In at least 1 billion – or almost half – of these cases, vision impairment could have been prevented or has yet to be addressed. These 1 billion people include those with moderate or severe distance vision impairment or blindness due to unaddressed refractive error (88.4 million), cataract (94 million), age-related macular degeneration (8 million), glaucoma ('i.'i million), diabetic retinopathy (3.9 million), as well as near vision impairment caused by unaddressed presbyopia (826 million). In terms of regional differences, the prevalence of distance vision impairment in low- and middle-income regions is estimated to be four times higher than in high-income regions.

eyeSmart EMR

eyeSmart is a national and international award winning ophthalmic Electronic Medical Record (EMR) and Hospital Management System developed by the L V Prasad Eye Institute, India. The digital system integrates the hospital's clinical, surgical, financial and operational functions on a single seamless platform. The eyeSmart Digital app helps rural eye care providers to screen for vision impairment in the community and detect common ocular diseases like refractive errors, cataract, diabetic retinopathy, and others. It helps to document important clinical information and also integrates state-of-the-art tele-ophthalmology tools which are helpful in reducing the risk of vision loss for the patients. The app enables screening of populations who live in rural areas and who are at risk due to lack of knowledge, high cost of eye care services, and geographical barriers. The App enables Vision Centre Support, Community Screening, School Screening, Tele-Ophthalmology, and Primary Eyecare Integration (see https://eyesmartemr.com/)

LVP Eye Innovations evolved out of the LVP-MITRA program, a collaboration between the L V Prasad Eye Institute and the MIT Media Labs. The following are three examples of products that have been developed to tackle screening for refractive errors. (Folding Foropter) evaluates visual field to detect glaucoma (OM) and has screened over 100,000 eyes, and enables anterior segment imaging (Grabi) that helps to take an external picture of the eye by the patients. Currently the devices are being used internally in LVPEI by the vision guardians, vision technicians and patients visiting our centres across the network.

Building the App

The initial prototype of the app was developed using a tablet computing device at a hackathon organized by LVPEI and the MIT Media Lab in 2014. We then continued the app development with internal resources and connected the app to eyeSmart EMR in 2015. The app was developed to tackle the dual challenges of the lack of reliable

internet connectivity and unstable power. The developed system allowed LVPEI's staffat the rural centres to seamlessly digitize patient data collected in the village vision centre on the tablet and sync the data using a 3G SIM card.

Scaling the App & Challenges

We deployed the app first in Bijnapally village in Telangana and then in nine more vision centers in the Thoodukurthy cluster within a month in 2016. The team faced enormous resistance to change from the existing paper-based system and made multiple visits to the field to educate the staff at the vision centres on the importance of digital transformation. We were mindful and cautious of "the danger of a single story" in any major implementation. No matter how good the solution was, the first roll-out might face user resistance and fail to elicit favourable feedback for many reasons. Hence, it was essential to roll out the app at a few other sites to understand user behaviour.

We realized that the only way to showcase the true benefit of the eyeSmart EMR app was to rapidly roll it out across the vision centres of LVPEI and use the ensuing success to counter detractors. The process of digital transformation is an art and happens at a multisensory level for the user. There are three types of users during any implementation: supporters, observers, and detractors. The key is to effectively showcase the user experience of the supporters to the observers and quickly achieve the critical tipping point of adoption. The next step is to convert the observers into supporters, who would then constitute the majority of the staff. Upon reaching this point, the detractors would have no option but to fall in line in due course of time.

In 90 days, from January to March 2017, the team deployed the eyeSmart EMR app across about 200 vision centres within the LVPEI network. To our surprise, the team found a significant number of supporters, which enabled a successful roll-out across LVPEI's vast network of vision centres in just three months. Over time, the eyeSmart EMR app clocked in over 1.7 million patients and streamlined tele-ophthalmology requests, saving time and money for patients in rural areas. We see over 2,000 patients on the eyeSmart App in rural villages and conduct over 250 Teleconsults every single day.

Limitations of EMR

The most important aspect of any technological system is the human component. The discipline of entering healthcare data into structured forms is of utmost importance. The digital systems must be supported by regular clinical audits to ensure that there is a constant check on the input of data. We also have a massive student base that keeps changing every 6 months, so it is all the more important to perform regular audits and educate the users on the input of information. We have understood that 10-15% of the data is noise and might not be used for research purposes. Different users have unique patterns in the input of information and we check for keywords in various aspects of the clinical forms. There has to be a mandate and support from the leadership of any organization to undergo Digital Transformation. This is crucial to enable change management across the entire user base.

Biography

Anthony Vipin Das is an Ophthalmologist by passion and an Innovator by choice. He completed his Post Graduate Training in Ophthalmology from Kakatiya Medical College, Warangal. He then pursued a short-term fellowship in Oculoplasty under Dr Julie Woodward at Duke University, Durham, USA. He is also a Fellow of the Royal College of Surgeons and Physicians, Glasgow. His specific interests include Ocular Trauma and Community Ophthalmology and he is currently pursuing research in the field of Regenerative Medicine and Eyeball Transplantation. He has presented widely both on National and International Platforms.

Dr Vipin is the Team Principal and Chief Architect of eyeSmart EMR, a revolutionary award winning Electronic Medical Record and Hospital Management System developed in-house at LVPEI. The system is currently operational at varied platforms in the LVPEI Network, such as City Centres, Tertiary Centres, Secondary Centres and Village Vision Centres and has checked in over 310,000 consultations over 3 years. He is also the Founder of REPOrT (Rural Education and Prevention of Ocular Trauma) which has addressed over 20,500 rural children in the prevention of Ocular Trauma and is an ongoing project.

He is a Member of the International Task Force for Emerging Technologies for Teaching and Learning at the International Council of Ophthalmology (ICO) and is passionate about developing meaningful ophthalmic educational content on the Internet. He served as an Advisor on Healthcare Innovation to the Ministry of Medical, Health and Family Welfare, Government of Telangana, India. He is the Principal Investigator and Mentor of projects in the visual rehabilitation space such as the Braille Phone, FITTLE and LeChal - the Haptic shoe for the Blind. He is a TED Senior Fellow and is named among the Top 35 Innovators under 35 years of age in the world (TR35 2012) by the Massachusetts Institute of Technology, USA.

7. Determining optimal ways to monitor and detect diabetes in low-resource settings: Locally-relevant evidence from Uganda

Dr Anxious Niwaha

Although HbA1c and home capillary or subcutaneous glucose monitoring are the primary measures used to monitor glycaemic control and guide treatment titration in diabetes in high-income countries, these approaches are often unavailable or unaffordable for people with diabetes who live in Uganda. Even where available, there has been substantial concern that HbA1c measurement may be unreliable in African populations, due to high prevalence of haemo-globinopathies such as sickle cell and other comorbidities that may affect test reliability including anaemia and malaria. Home glucose monitoring is not funded by the Uganda healthcare system, and is beyond the financial means of most of those who have diabetes. Current clinical practice varies with fasting glucose used by many clinicians, but others routinely use non-fasting 'random' measurements. In Uganda, diabetes clinics are operated at regional and district hospitals, and access to transport services is unreliable or unaffordable. Therefore, many patients will walk long distances to attend these centralized diabetes clinics every 2 – 3 months.

The aim of our research group is to determine the most accurate and cost-effective way to diagnose and monitor diabetes in Sub-Saharan Africa (SSA). In the OPTIMAL study, we aimed to compare, in an African population with type 2 diabetes, the accuracy of fasting plasma glucose (FPG), random non-fasting plasma glucose (RPG), glycated albumin, serum fructosamine and HbA1c in comparison to continuous glucose monitoring (CGM) as an independent measure of glycaemic control, and assess the impact of other medical conditions that may affect HbA1c reliability to monitor glycaemia in people with established diabetes. As part of the OPTIMAL study, we also determined the assay reliability of HbA1c measurement on the different methodologies (including point-of-care HbA1c) in the presence and absence of haemoglobin variants. To assess whether the reliability of fasting glucose for monitoring glycaemic burden is unlikely to be altered in patients who walk to the clinic, we designed a randomized crossover trial. In the ongoing DOP study we are assessing the reliability of fingerstick versus laboratory measured venous plasma in measuring glucose burden.

The key findings from our projects are:

- HbA1c is the optimal laboratory method for assessing glycaemic control, even in populations with high prevalence of conditions reported to affect test reliability.

- We observed a strong correlation (r>0.80) between the mean CGM glucose and the different HbA1c methodologies even among individuals with sickle cell trait. The average bias in HbA1c measurement between the three methodologies (HPLC, immunoassay, boronate affinity (point-of-care)) was 2 mmol/mol (2.07%) when compared to a capillary method.FPG and RPG measurement correlate strongly with both CGM and HbA1c, perform reasonably well in identifying poor glycaemic control, and can therefore be used when HbA1c is unavailable.

- Switching to glycated albumin (GA) or fructosamine would not improve the accuracy of glycaemic monitoring among African type 2 diabetes patients above and beyond HbA1c. Therefore, these findings do not support recent recommendations from diabetes organisations such as ADA to use fructosamine and glycated albumin as alternative glycaemic control markers in patients for whom HbA1c is unreliable.

- The accuracy of HbA1c (measured by HbA1c immunoassay), GA and fructosamine in reflecting glycaemic control is not affected by sickle cell trait. In contrast, in those with anaemia or renal impairment, HbA1c, fructosamine and GA may all be unreliable in reflecting the glycaemic burden.

- Fingerstick values showed a modest bias towards lower fasting glucose than laboratory-measured glucose, with laboratory values, 0.28 (95% CI: 0.23, -0.34) mmol/L higher. 2-hour post OGTT fingerstick and laboratory glucose were highly correlated (0.92, 95% CI: 0.91 – 0.94): fingerstick values showed a modest bias towards higher post-Oral Glucose Tolerance Test (OGTT) than laboratory glucose, with laboratory values 0.60 (95% CI: 0.53 – 0.66) mmol/L higher.

The findings from our projects suggest that HbA1c is the overall best measure of glycaemic burden, despite the high prevalence of other medical conditions that may affect its accuracy (especially anaemia and renal impairment). In settings like this where patients do not own personal glucometers, and patients are reviewed by clinicians once in 2-3 months, HbA1c has the potential to optimize patient management since it shows the glycaemic burden over the past 2-3 months.

HbA1c however is not available in most health facilities and is not easily affordable by majority of the patients. Our results showing that the point-of-care HbA1c test performs well in reflecting glycaemic burden are reassuring. Studies assessing the cost-effectiveness of implementing HbA1c point-of-care testing (which has a quick turnaround time for HbA1c results) at health care facilities are needed in order to scale up their use in low-resource settings and to inform policy. In addition, we would like to assess the diagnostic utility of point-of-care HbA1c in Uganda and other low-income countries where the highest proportion of individuals with undetected diabetes reside and resources are limited.

Biography

Anxious Niwaha is a clinician and research scientist with the Department of Non-communicable Diseases (NCDs) at the MRC/UVRI & LSHTM Uganda Research Unit Entebbe. He has more than 8-years combined clinical and research experience in infectious diseases such as HIV/TB and NCDs including hypertension and diabetes. He is a graduate of Makerere University School of Medicine and holds a PhD training in Clinical diabetes from the University of Exeter (UK). Most recently he defined the comparative performances of the commonly used tests for monitoring diabetes; fasting glucose, random glucose, glycated haemoglobin (HbA1c) and other novel tests namely; glycated albumin, and fructosamine in Uganda.

His current research focuses on diagnosis and characterisation of diabetes in low-resource populations; where he is examining the diagnostic utility of point-of-care tests (POCT-HbA1c and Glucometer). Dr Niwaha is also interested in further exploring whether factors particular in Africa such as non-glycaemic conditions (anaemia, haemo-globinopathies, infections; malaria, HIV and TB) might impact the reliability of HbA1c.

8. AHOMKA: Advancing Hypertension Health Outcomes in LMICs with Culturally-adapted Mobile Technology

Dr Jacques Kpodonu

The AHOMKA Research and Education Network is a collaborative partnership between researchers and medical device professionals with expertise in mobile technology development, hypertension, cardiology, population studies, and public health across multiple institutions in Ghana (University of Ghana, University of Health and Allied Sciences, Medtronic Labs Ghana) and the USA (Beth Israel Deaconess Medical Center, Tufts University). AHOMKA is funded through the US National Institutes of Health (NIH) National Institute of Biomedical Imaging and Bioengineering (Grant No. R21EB033166) and the Fogarty International Center's Mobile Health Technology Outcomes in Low and Middle Income Countries Program.

Project Objectives and Goals

The objective of this multi-disciplinary partnership is to develop the AHOMKA mobile platform, an evidence-based, multi-faceted mobile health intervention with the overall goal to reduce the prevalence of uncontrolled hypertension in Ghana. AHOMKA is an adaptation of the Empower Health™ mobile platform developed by Medtronic, the global leader in the medical device industry, as a new task-sharing model of care for chronic diseases, consisting of a mobile application for patient data tracking, provider-to-patient communication, and community-based chronic care management Our primary objectives are to (1) develop the AHOMKA mHealth platform by conducting an iterative, adaptive design process with patients, healthcare providers and software developers in an urban and rural region of Ghana; (2) assess the usability and feasibility of the mHealth intervention in the clinical setting and (3) establish the AHOMKA mHealth Research and Education Network for long-term collaboration between research institutions, industry partners, public health policy makers, and clinicians to strengthen mHealth capacity in Ghana with respect to management of cardiovascular disease.

Potential Impact

Over the past decade, LMICs have experienced a rapid increase in the burden of chronic diseases, resulting in major strains on fragile health care systems facing serious shortages of healthcare providers (Abdulai, 2017). The COVID-19 pandemic has accelerated the use of remote monitoring technologies globally to reduce exposure rates. However, there remains a wide gap between high- and low-income countries in assessing and evaluating mHealth programs (Karageorgos, 2019). The AHOMKA project will design and assess an evidence-based, mHealth intervention for hypertension management using a mHealth platform tailored to the local cultural context of patients in two regions of Ghana. The program is expected to have a significant and sustained impact on reducing the prevalence of uncontrolled hypertension in Ghana and reducing morbidity and mortality rates associated with hypertension. The proposed capacity building initiatives will have a long-term impact on mHealth research, interventions, assessment strategies, and policies in Ghana and

the entire West African region. In collaboration with the Ghana Health Service, we will establish the first data repository for mHealth research in Ghana.

Regional Significance

Our multi-site study is being conducted at the cardiothoracic centers at teaching hospitals in two regions of Ghana: Korle-Bu Teaching Hospital in the Greater Accra Region and the Ho Teaching Hospital in the Volta Region. These regions where chosen due to the contrasting demographics of the regions. The Greater Accra Region is home to the capital city of Ghana (Accra) and is the second most populated region with a population of 4,010,054 in 2010, accounting for 16.3% of Ghana's total population. The Greater Accra region is the most urbanized region in the country with 87.4% of its total population living in urban centers. The Volta Region's capital city is Ho with a regional population of 2,118,252 in 2010. The largest native ethnic group of the Volta Region is the Ewe people (68.5% of the population). Nearly 40% of the Volta Region's population lives in rural areas.

Innovation

The AHOMKA program involves several layers of innovation that build on existing, evidence-based chronic disease management tools to adapt and assess a mobile technology platform to guide hypertension management. The proposed AHOMKA study is centered around a modified version of Empower Health™, a novel social venture initiative developed by Medtronic Labs. The Empower Health™ platform is a novel chronic condition management model of care consisting of hardware and a proprietary software application. A conceptual diagram of Empower Health™ can be found in Figure 1. The platform enables health care providers (HCPs) to manage a cohort of hypertensive patients remotely; and patients are able to track blood pressure recordings, treatment plans, and receive text messages from providers. The Empower Health™ platform includes a rich set of features:

1. *Patient-facing Mobile Application and Messaging Service*: The current Medtronic Empower Health™ platform uses Short Messaging Service (SMS), and a smartphone app for patient access to the system to record BP readings and to receive messages from the clinic. In this project we will integrate Unstructured Supplementary Service Data (USSD) to enable patient access across a wide range of mobile phone platforms.

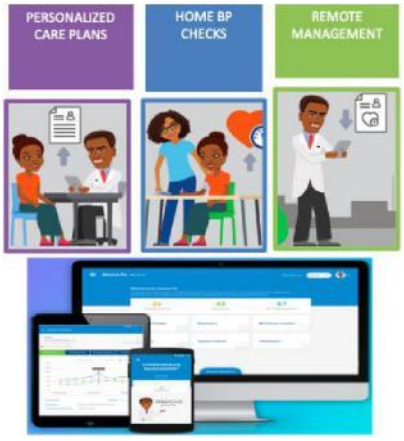

Figure 1. Medtronic Empower Health™platform.

2. *Provider-facing Mobile Application*: Healthcare providers have the ability to collect basic clinical data, provide patients with earlier detection of elevated BP, remotely guide hypertensive patients to connect directly with their HCP when further clinical evaluation is needed. Providers can monitor patient data using a customized mobile app and access data on a tablet, mobile phone, or web-based portal. Communication with patients is currently enabled by short messaging services (SMS) and will be expanded to USSD.

Key Issues

We are currently in Phase I of the project, which includes a qualitative acceptability study with patients and providers at the two sites. We have successfully enrolled 32 patients in the study, including technical training on the Empower Health mobile application, blood pressure recording tutorials, in-depth interviews, and a 4-week assessment of the platform. We encountered technical issues with the mobile platform that required coordination with the Medtronic software development team, which is spread out over several countries. Technical challenges caused several delays in enrolling patients in our study and recording data on patient interaction with the mHealth platform.

Main Outputs:

Summary statistics of acceptability scores by study site among study participants

Component	Highest score	Study site		
		KBTH	Ho	Overall
		Min-Max	Min-Max	Min-Max
Effort Expectancy	100%	35.56-62.80	27.78-55.02	27.78-62.80
Performance Expectancy	100%	37.04-60.39	33.15-60.39	33.15-60.39
Social Influence	100%	52.16-61.74	49.81-56.97	49.81-61.74
Facilitating Conditions	100%	39.79-67.02	45.84-50.38	39.79-67.02
Overall	100%	45.91-70.22	40.62-51.19	40.62-70.22

NOTE: Abbreviation; Min=Minimum score; Max=Maximum score

Discussion and Future Work

The overall response to the Empower Health platform from patients and care providers has been enthusiastic. We have established interactive engagement with the technical support team to resolve issues in a timely manner to avoid delays in our study. In Phase II of this project, we are planning to adapt the platform to enable bidirectional communication between patients and providers using Unstructured Supplementary Service Data and SMS text messaging.

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Biography

Jacques Kpodonu is an international cardiac surgeon at Beth Israel Deaconess Medical center and Assistant Professor of Surgery at Harvard Medical School. His clinical interests include structural heart and aortic disease with particular intersects in hypertrophic cardiomyopathy (HCM), the most common genetic heart disease in the USA and global cardiac surgery capacity in LMIC.DR. Kpodonu' research is focused on addressing cardiovascular health disparities by researching artificial intelligence

algorithms from EKG, cardiac echocardiograms and biomedical devices innovation including organ on chip technology for modelling heart disease, wearable technology and heart valve technology development.

Dr Kpodonu is editor of 5 textbooks including "Global Cardiac Surgery Capacity development in LMIC". Dr Kpodonu holds leadership positions with the Society of Thoracic Surgery, American College of Cardiology, Association of Black Cardiologists and on the editorial board of the Annals of Thoracic Surgery

9. Scaling up of a primary care intervention for cardiovascular risk management in Indonesia

Dr Praveen Devarsetty

SMART (Systematic Medical Appraisal, Referral and Treatment) health is a technology- enabled ecosystem that aims to improve the delivery of consistent high-quality essential primary healthcare to communities. Built on extensive prior and ongoing work in Australia, China and India, SMARThealth supports the provision of preventive care at the community and household level by strengthening existing health systems.

SMARThealth was initially designed with a focus on cardiovascular disease (CVD), but is expanding into many other disease areas. Initially SMARThealth was delivered in 4 villages in the Malang district, East Java, Indonesia over a 12-month period and evaluated using a mixed methods using the RE-AIM framework. This was later progressed to the next phase of "proof-of-concept" scale-up where it is being implemented in 104 villages and currently being scaled up to cover all 390 villages in Malang district, funded by the Malang district health agency, with technical assistance and evaluation provided by the George Institute and University of Brawijaya.

During the session, I will discuss early learnings from this scale-up phase emphasizing the overarching enablers and barriers for scaling up digital health innovations in LMICs.

Biography

Praveen Devarsetty is a public health specialist with thorough knowledge of epidemiological study designs and having a keen interest in systems-based innovations to address inequities related to chronic diseases.

His research experience is related to planning and managing large scale public health research projects and surveys. He is currently leading the SMARThealth program in India and Indonesia that aims to bridge the implementation gap in blood pressure control for individuals with high risk of cardiovascular diseases using technology and task-sharing.

He is the head of the primary healthcare research at The George Institute India, based in Hyderabad. He has been awarded the competitive Australian Leadership Awards Scholarship in 2012 to pursue his PhD in the University of Sydney. His current focus is on health systems and in understanding the system level barriers to address health system delivery.

10. Using low-cost digital technologies to deliver novel clinical solutions

Prof. Andrew Farmer (Session Co-Chair)

This presentation will focus on lessons learned from work in Southern Africa and the UK around development and evaluation of digital healthcare innovations carried out in collaboration between engineers and clinicians.

Principles of working

One of the key principles underpinning the work reported here is the use of low cost-technologies used in a smart way – implemented in specific clinical pathways, making maximum use of data collected routinely, and considering usability for patient and clinician.

GDm -Health (Gestational Diabetes)

A gestational diabetes system, based on previous work linking glucose monitors and phones via Bluetooth, was developed to support women developing gestational diabetes to allow remote monitoring of blood glucose levels and adjustment of insulin treatment. A pilot study and a clinical trial confirmed that the system was seen as valuable by both patients and clinical staff, and while clinical outcomes were marginally more favourable for the system compared to usual care, the reduced number of visits to hospital for women, and the improved workflow for midwives resulted in a system that improved care. Further work explored roll-out of the system in NHS Trusts. Factors in adoption included the familiarity of the population with mobile technology and the ease of use by midwives. The system has been licensed and is in clinical use in over 60 UK hospital trusts.

SMS text messaging in Southern Africa

For the last 20 years, the role of SMS-text messaging in delivering programmes of education, treatment or support using brief messages, particularly focussing on using medication in line with recommendations. Whilst a well-established system of medication dispensing had been established in Cape Town, pick-up rates by patients at public clinics remained at around 50%.

The engineering team built a cloud-based system designed to register patients in clinic and then send regular SMS messages to patients with hints and tips for taking the medicines as recommended. The system was managed at low cost and able to handle cancellation and re-booking of appointments and changing the language of messages remotely. The system was seen as acceptable and helpful. In a trial, the blood

pressures of those receiving messages dropped by a small amount compared to a standard control group. Whilst innovative, the system itself was not felt suitable to scale up.

Discussions with commercial SMS providers and the Health Departments identified continuing interest in the use of text-messages, but the model of implementation needed to be through a commercial provider. The South African federal government

mandated further studies of messaging and established the Mom-connect model (messaging for pregnant women) which was rolled out at scale nationally. This was widely recognised as an innovative approach, but has not been adopted elsewhere.

The SMS text messaging model has been further developed and evaluated in the UK using established text messaging services linked to research systems. The UK focus has been on people with type 2 diabetes and on developing messages that have a strong foundation in health psychology theory to support medication adherence. Findings from this programme of work have identified: (i) SMS messages are less likely to be useful to people who have already received diabetes education, but to those newly diagnosed they are an additional route to providing information; (ii) in a setting where health education resources are widely available, the incremental effect of SMS messages may be small, but it is unclear whether they could allow more targeted use of intensive educational resources.

Next steps

Current work from our group is focussed on monitoring technology following hospital admission or to support home care for acutely unwell individuals.

These include the use of vital signs (pulse, respiration rate, accelerometer and one-lead ECG) that have previously been deployed in a hospital setting to minimise nurse contact with COVID patients. The aim of this work is understanding how to insert the technologies into clinical pathways where they can provide early warning of clinical deterioration and guide management decisions.

Biography

Andrew Farmer is Professor of General Practice in the Nuffield Department of Primary Care completed his specialist training in the Oxford Deanery and then worked as a full-time general practitioner at Thame Health Centre for 17 years. He was a GP trainer, contributed to practice development, and began to develop an interest in research. In 1991 he was one of the first general practitioners to be awarded a Harkness Fellowship from the Commonwealth Fund of New York. He subsequently completed a higher degree and then moved to the Oxford University Nuffield Department of Primary Care Health Sciences, funded through an NHS R&D Senior Clinical Scientist Award in 2001. He took up his current university post in 2007.

His research interests are focused on improving the health and wellbeing of people with chronic and long-term health conditions. Much of his work has centred on improving the self- management of diabetes in general practice. This has included researching where blood glucose monitoring is helpful, supporting people in making best use of their medicines, and developing and testing digital health systems. His research group uses a wide range of research methods including qualitative research, analysing electronic health records, and clinical trials to produce evidence. He is leads the National Institute for Health and Care Research (NIHR) Oxford Biomedical Research Centre Digital Health from Hospital to Home theme. He has an h-index of

60. He was appointed NIHR Senior Investigator Emeritus in 2021 and holds the title of Honorary Professor in the Department of Medicine at the University of Cape Town.

Andrew works as a general practitioner at St Bartholomew's Medical Centre. He was appointed a member of the Health Technology Assessment (HTA) Commissioning Funding Board in 2001, Deputy Chair of the HTA Commissioning Board in 2007 and Chair of the HTA General Funding Committee in 2016. He has held a wide range of other research management roles including as the founding director of the UKCRN registered Primary Care Clinical Trials Unit at Oxford, Clinical Lead for the NIHR Thames Valley Diabetes Research Network, Co- Director of the NIHR Thames Valley Comprehensive Local Research Network and Panel Chair for NIHR Programme Grants for Applied Research. He took up the role of Director of the NIHR HTA Programme in October 2020.

Session 7: Challenge of implementing and scaling up resources in LMIC settings

1. Sustainable POC Diagnostics Services for LMICs – Focus on Blind Spots

Prof. Tivani Mashamba-Thompson

Scale-up and optimal implementation of new point-of-care (POC) diagnostics is a global health priority. Adoption of new evidence-based POC diagnostics to replicate and extend the reach of diagnostics to those who need it the most is key to achieving universal health coverage.

Our research group REASSURED-d@UP focuses on optimising the implementation of POC diagnostics for resource-limited settings and underserved populations. Aided by transdisciplinary research, we have identified priority factors for ensuring sustainability of POC diagnostic services in LMICs. Our research revealed the need improve quality systems management, supply chain management and diagnostics literacy to ensure sustainability access and implementation of POC diagnostics in these settings. We also emphasise the need for advancing diagnostic enabling technologies such as mobile health technology and artificial intelligence.

As exposed by the COVID-19 pandemic, equitable access to POC diagnostics services is essential for ensuring rapid disease diagnosis, surveillance and management. Our COVID-19 response risk communications research established the need to improve diagnostics literacy among all stakeholders. Diagnostic literacy encompasses a broad range of factors that are closely related to health promotion, including culture, individual empowerment, community development, media and numeracy. We argue that improved diagnostic literacy will boost sustainable implementation of POC diagnostics in LMICs.

Biography

Tivani Mashamba-Thompson is a Molecular Biology Medical Scientist (registered by the Health Professions Council of South Africa) with a Master's degree in Pharmaceutical chemistry (summa cum laude) and PhD in Public Health. She completed a Global Clinical Research Program at Harvard Medical School and her postdoctoral fellowship under the Canadian HIV Clinical Trials Network. She is a Professor of Diagnostics and a Deputy Dean of Research and Postgraduate Studies for the Faculty of Health Sciences, University of Pretoria. She is the founder and lead researcher for REASSURED-d@UP. She is a co-Director for University of Pretoria MartiTB Diagnostics PTY(LTD), University of Pretoria. She serves as a non-executive board member of the National Health Laboratory Services (NHLS) as a Deputy Chairperson of the NHLS Research and Innovation Committee. A member of the Department of Health Office of Health Standards Compliance Technical Task team and a diagnostic's expert advisor for Abbott International.

Prof Mashamba-Thompson was awarded the 2022 South African Medical Research Council (SAMRC) Scientific Merit Award. She is also an NHS-trained medical sciences researcher.

2. Social Entrepreneurship

Mr Philip Wilson

The global South faces significant challenges in delivering clean water to its populations. Many communities in these regions do not have access to safe and reliable sources of water, leading to a range of problems including waterborne illnesses, malnutrition, and reduced economic productivity. Traditional solutions such as building large centralized treatment plants and piping systems are often not feasible due to financial and logistical constraints.

Ecofiltro is a social enterprise that aims to address this problem by providing low-cost, decentralized water filtration systems to communities in the global South. The filtration system is able to remove 99.99% of bacteria and other contaminants from water, making it safe to drink. Their system uses locally-sourced materials - a combination of ceramic filters and biochar to purify water at the household level, providing a simple, effective and easy-to- maintain way to ensure access to clean water.

In addition to providing a vital service to communities in need, Ecofiltro also employs local workers and uses environmentally-sustainable materials, making it a socially and environmentally responsible approach to the problem of water access. Through its efforts, Ecofiltro has been able to bring clean water to hundreds of thousands of people in Central America and Africa.

In this talk I will talk about how we came to build the open-source model for Ecofiltro.

Biography

Philip Wilson is the founder and CEO of Ecofiltro, a social enterprise dedicated to providing clean water to the rural poor of Mexico and Central America. He graduated with an MBA from Wharton and a BA from Notre Dame. He has over twenty-five years of experience as an entrepreneur in the United States and Guatemala, and firmly believes that the world's most pressing problems can be solved by applying business practices to social challenges. He is the founder and CEO of SolucionWeb, the leading web and social media services company in Guatemala.

Wilson is a member of the board of the Guatemalan Center for Corporate Social Responsibility, was named "Social Entrepreneur of the Year for Central America" by the Schwab Foundation in Davos, Switzerland and "One of the 10 most successful Social Entrepreneurs in Latin America" by New Ventures Mexico. To date, over 500,000 families in rural areas have been served by Ecofiltro and the goal is to reach 1 million families by the year 2025. In 2022, Philip founded El Cubo, an entrepreneurial center whose purpose is to help entrepreneurs create and grow companies in Guatemala. Philip is also an adjunct Professor at Emory University, teaching at the Co-Design Lab for Health Equity.

3. Leveraging Electronic Medical Records for Diagnostics in LMICS: A case of UgandaEMR in Uganda

Dr Stephen Senkomago Musoke

The democratization of diagnostics within patient centered care in LMICs can be achieved by building on the successes of rolling out electronic medical records systems (EMRs) in public health facilities that provide healthcare to the majority of the population. A large majority of the facilities have high patient loads, both in-patient and out-patient thus providing a perfect storm to adopt approaches that can provide clinicians with a single view of the patient at any time.

The lessons I will share are based on over 6 years of designing, developing, evolving, rolling out and supporting UgandaEMR in Uganda across 1,300 public health facilities. UgandaEMR is a nationally-approved EMR based on OpenMRS, leveraging US PEPFAR funding for HIV care in a collaboration between Makerere University and University of California San Francisco, USA. Initially focused on collecting program monitoring and evaluation data, it has evolved to provide patient-centered focus through point-of-care/point-of-service data collection by clinicians, counsellors, laboratory technicians, and other facility health care staff. It includes a community extension and follow-up through UgandaEMR Mobile, a custom-built Android based application.

UgandaEMR submits data to centralized databases through a Health Information Exchange (HIE) based architecture for M&E and surveillance purposes. The centralized data set with patient level records is anonymized and transformed into data for surveillance analytics. This can be leveraged to train AI/ML algorithms that can later be deployed at facility level to provide immediate feedback including alerts to clinicians and care providers. Future integrations are looking at a direct machine interface opening the possibility of collecting data from diagnostic bedside machines directly into public health facility EMRs. A key success factor for UgandaEMR is the growing maturity of an information and technology savvy healthcare workforce.

Biography

Stephen Senkomago Musoke has been working in the software development industry for over 20 years. He led the design, development and rollout of UgandaEMR, one of the Ministry of Health (MoH) approved electronic medical records systems, that is based on OpenMRS, under the Monitoring and Evaluation Technical Support (METS) program a CDC-funded strategic information implementing partner a collaboration between Makerere University School of Public Health and University of California San Francisco.

UgandaEMR rollout started with an upgrade of 350 public health facilities (2016) to over 1,400 sites (December 2022) covering HIV care and treatment, HIV Exposed Infants, TB, Antenatal/Maternity/Postnatal care, VMMC, COVID19, Cervical Cancer with retrospective data entry, point of care service provision and community support extensions. The roadmap for UgandaEMR involves data sharing through a health

information exchange (HIE) compatible architecture for disease surveillance and national level M&E from patient level data.

5. EHRs in LMICs

Dr Hamish Fraser

Clinical diagnosis is a critical skill that is foundational for effective clinical care and disease surveillance. Mis-diagnosis is a leading cause of medical errors and poor outcomes world-wide. High-quality diagnosis is especially challenging in low-income settings which typically deal with very short consultation times, limited access to diagnostic tests, and serious shortages of well-trained clinical staff. A critical part of improving diagnosis is being able to document clinical data and access it at point of care, the core function of an electronic health record (EHR). These systems have been deployed at scale over the last 5-10 years in several low-income settings, primarily for chronic disease management, and need to be extended to effectively address primary care and urgent care consultations. Combining core clinical data, point-of-care diagnostics, and any previous clinical data including mobile health interactions, will allow immediate benefits in diagnosis and the ability to track quality of care.

Such EHR systems can also include diagnostic decision support systems targeted at health care workers and/or patients which can augment decision making as long as they are monitored and evaluated for safety, effectiveness and clinical efficiency. They will also allow effective development and safe and equitable deployment of machine learning techniques for the majority of clinical interactions in low-income settings.

I will describe the state of EHR development and deployment in low-income countries using examples of the OpenMRS open-source EHR that has been adapted locally for the needs of many countries. Building on the other presentations in this session and my recent work in Kenya, I will also address the design for an EHR that supports optimal clinical diagnosis in all environments and the small but important remaining gaps in achieving this vision.

Biography

Dr Fraser is Associate Professor of Medical Science, Associate Professor of Health Services, Policy and Practice at Brown University. He trained in General Medicine, Cardiology and Knowledge Based Systems at Edinburgh University, in Scotland, and in Clinical Decision Making at MIT and the New England Medical Center. His work has led to the migration of medical informatics tools and expertise from high income countries to some of the most challenging environments in low income countries. As Director of Informatics at the leading Healthcare NGO Partners In Health, he co-founded OpenMRS an open source Electronic Health Record project.

He was also an Assistant Professor of Medicine at Harvard Medical School from 2006 - 2015. He has co-created and taught courses in Global eHealth at Leeds University, Edinburgh University and MIT, and co-authored a text book on this field. His main academic focus is in the evaluation of medical information systems particularly in Low and Middle Income Countries, and understanding the impact of information and communications on quality of healthcare worldwide. He also focusses on improvement of care for non-communicable diseases particularly Heart Disease.

Dr Fraser was the Co-PI and Informatics and evaluation lead for a grant from the US CDC to evaluate the functioning, clinical impact and costs of an OpenMRS based EMR system for HIV care in Rwanda. He has previously held grants as PI from the CDC, the Rockefeller Foundation and IDRC for eHealth work in Rwanda. From 2015-2017 he held a Marie Skłodowska-Curie Fellowship from the European Union Horizon 2020 program.

In 2021 He received an R01 grant as Co-PI with Professor Hogan at the Brown University School of Public Health and Ann Mwangi at Moi University in Kenya, entitled "Data Science for Decision Support in the HIV Care Cascade". This project will build prediction models using machine learning techniques and deploy them using the OpenMRS EHR with the goal to improve HIV care in Western Kenya. The use of the new system will be evaluated in a cluster randomized, controlled trial. Dr Fraser's recent work at Brown includes leading an evaluation study with Dr Megan Ranney of a diagnostic app or "Symptom Checker" from Ada Health being used by patients in the ED at Rhode Island hospital. He is also completing a study with Dr Ross Hilliard and colleagues in the evaluation of the Ada app with 200 patients in a setting seeking urgent primary care. This work is being extended to focus on the out-of-hospital diagnosis of stroke using two large data sets of possible stroke patients. This work is funded by an OVPR Seed grant from Brown University.

Session 8: What have we learnt?

Prof. Lionel Tarassenko

Professor Lionel Tarassenko CBE FREng FMedSci is the founding president of Reuben College, and Theme Lead for the AI & Machine Learning research cluster. He is an expert in the application of signal processing and machine learning to healthcare, with a strong track record in translation to clinical medicine. His work has had a major impact on the identification of deterioration in acute care and on the management of chronic disease. The system which he designed for patient monitoring in critical care was the first machine learning system to gain FDA approval (in 2008). Prior to that, Professor Tarassenko had been closely involved in the development of some of the jet engine monitoring software at the core of the Rolls-Royce TotalCare® package. This won him the Rolls-Royce Chairman's Award for Technical Innovation in 2001 and the Sir Henry Royce High Value Patent Award in 2008.

Professor Tarassenko was appointed University Lecturer and Tutorial Fellow in Oxford (St Hugh's College) in 1988. He was elected to the Chair of Electrical Engineering and to a Professorial Fellowship at St John's College, also at the University of Oxford, in 1997. He was the driving force behind the creation of the Institute of Biomedical Engineering (IBME) which he directed from its opening in April 2008 to October 2012. Under his leadership, the IBME grew from 110 to 220 academic researchers, and it was awarded a Queen's Anniversary Prize for Higher Education in 2015 for "new collaborations between engineering and medicine delivering benefit to patients". He was then the Head of the Department of Engineering Science (Dean of Engineering) from 2014 to 2019.

Professor Tarassenko was elected to a Fellowship of the Royal Academy of Engineering in 2000, and to a Fellowship of the Academy of Medical Sciences in 2013. In 1996, he was awarded the British Computer Society (BCS) Medal for development of neural network analysis of sleep disorders. His work on mobile phones for healthcare was awarded the E-health 2005 Innovation Award for "best device to empower patients". He received the 2006 Silver Medal of the Royal Academy of Engineering and he won the IET's IT Award, also in 2006. In 2010, he gave the Vodafone lecture on m-health at the Royal Academy of Engineering and the Centenary Lecture on Biomedical Engineering at the Indian Institute of Science in Bangalore. He received the 2015 Martin Black Prize from the Institute of Physics for the best paper in Physiological Measurement.

Professor Tarassenko is the author of 280 journal papers, 230 conference papers, 3 books and 32 granted patents (h-index = 84). He is the senior director of the University's wholly owned technology transfer company, Oxford University Innovation, and has founded four University spin-out companies (the latest being Oxehealth). He was the Editor-in-Chief for the Topol Review of NHS Technology and its impact on the workforce.